UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

MICHAEL LANE, Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., SANOFI US SERVICES INC., CHATTEM, INC., PFIZER, INC., AND GLAXOSMITHKLINE, LLC Defendants.	:	CIVIL ACTION NO.: **COMPLAINT AND JURY DEMAND**

COMPLAINT AND JURY DEMAND

COMES NOW, Michael Lane, by and through undersigned counsel, and files this Complaint against Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Sanofi US Services Inc., Chattem, Inc., Pfizer, Inc., and GlaxoSmithKline, LLC, (hereinafter collectively referred to as "Defendants") for personal injuries suffered as a result of Mr. Lane's use of Defendants' Zantac/ranitidine, which were manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

I. INTRODUCTION

1. Zantac, the brand name version of the chemical ranitidine, (generics and name brand Zantac are herein collectively referred to as "Zantac") prior to its recall, was used by millions of individuals to treat gastrointestinal conditions like acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease. Sales of Zantac in the United States since its introduction in 1983 have reached over $1 billion.

2. Zantac contains N-Nitrosodimethylamine ("NDMA"), a chemical recognized as a potent carcinogen. Formerly a chemical biproduct of making rocket fuel in the early 1900s, the

dangers of NDMA have been publicly known for over 40 years. Both the World Health Organization and the Environmental Protection Agency recognize NDMA as carcinogenic.

3. Zantac, as well as generic bioequivalent formulations of ranitidine, were available in both prescription and over-the-counter form. When used as prescribed or recommended, Zantac leads to the production of staggering amounts of NDMA when digested by the human body. The U. S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 ng (nanograms) and yet, in a single dose of Zantac, researchers are discovering over 3 million ng.

4. Recent discoveries of these dangerous findings spurred widespread recalls of Zantac by numerous manufacturers both domestically and internationally. The current owner and controller of the Zantac new drug applications ("NDAs") has recalled all Zantac in the United States. FDA is actively investigating the issue, with its preliminary results showing "unacceptable" levels of NDMA within the products. The presence of NDMA in Zantac is not due to contamination or manufacturing error, but a function of the ranitidine molecule and the way it breaks down in the human digestive system.

5. Plaintiff Michael Lane took Zantac for approximately five years and, as a result, developed bladder cancer. His cancer was caused by NDMA exposure created by the ingestion of Zantac. This lawsuit seeks damages against the Defendants for causing Mr. Lane to develop cancer.

II. PARTIES

6. Plaintiff Michael Lane (hereinafter "Plaintiff") resides in Providence County, Rhode Island and is a citizen of Rhode Island and not of any other state.

7. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. BI is a citizen of Connecticut and Delaware and not of any other state. BI is a subsidiary of the German company Boehringer Ingelheim Corporation. BI owned and controlled the NDA for over-the counter ("OTC") Zantac between approximately October 2006 and January 2017 and manufactured and distributed the drug in the United States during that period.

8. Defendant Sanofi US Services Inc. ("Sanofi") is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807 and is a wholly owned subsidiary of Sanofi S.A. Sanofi is a citizen of Delaware and New Jersey and is not a citizen of any other state. Sanofi controlled the NDA for OTC Zantac starting In January

2017 through the present and manufactured and distributed the drug in the United States during that period. Sanofi voluntarily recalled all brand name OTC Zantac on October 18, 2019.

9. Defendant Chattem, Inc. ("Chattem") is a Tennessee corporation with its principal place of business located at 1715 West 38th Street, Chattanooga, Tennessee 37409. Chattem is a citizen of Tennessee and not a citizen of any other state. Chattem is a wholly owned subsidiary of Sanofi S.A., a French multinational corporation. Chattem distributed OTC Zantac for Sanofi throughout the United States until Sanofi's voluntary recall.

10. 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 and is not a citizen of any other state. In 1993, Glaxo Wellcome, PLC formed a joint venture with Warner-Lambert,Inc. to develop and obtain OTC approval for Zantac. That OTC approval was obtained in 1995. In 1997, Warner-Lambert and Glaxo Wellcome ended their joint venture with Warner-Lambert retaining control over the OTC NDA for Zantac and the Zantac trademark in the U.S. and Glaxo Wellcome retaining control over the Zantac trademark internationally. In 2000, Warner-Lambert was acquired by Pfizer who maintained control over the Zantac OTC NDA until December 2006.

11. Defendant GlaxoSmithKline, LLC ("GSK") is a Delaware company with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania 19112 and Five Moore Drive, Research Triangle, North Carolina 27709. GSK is a wholly owned subsidiary of GlaxoSmithKline, PLC, which is its sole member. GlaxoSmithKline, PLC is a citizen of the United Kingdom and is not a citizen of any state in the United States. GlaxoSmithKline, PLC is the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known as ranitidine. Ranitidine was initially developed by Allen & Hansburys Ltd. which was a subsidiary of Glaxo Labs Ltd. Allen & Hansburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule. In 1983, Glaxo Holdings Ltd. was awarded approval by the U.S. FDA to sell Zantac in the United States. Glaxo Holdings, Ltd. was later absorbed into Glaxo Wellcome, PLC. And then, in 2000, GlaxoSmithKline, PLC and GSK were created by the merger of Glaxo Wellcome and SmithKline Beechum. GSK, and its predecessors, controlled the prescription Zantac NDA between 1983 and 2009.Under Florida law, GSK is the innovator of Zantac and

through its negligence and willful misconduct caused the labeling on the OTC Zantac label to not include any warning for cancer.

III. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C.§ 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over each Defendant insofar as each Defendant is authorized and licensed to conduct business in the State of Rhode Island, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

14. Additionally, the Defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

15. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to this claim occurred within this judicial district.

IV. HISTORY OF ZANTAC AND RANITIDINE

16. Zantac was developed by Glaxo – now GlaxoSmithKline ("GSK") – and approved for prescription use by the FDA in 1983. 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. Ranitidine was specifically developed by Glaxo in response to the then leading H2 blocker, cimetidine (Tagamet).

17. 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, were highly likely to form the NDMA when combined with other substances, *i.e* nitrite, already found in the body. Indeed, nitrite is not only naturally found in the body, but bacteria and enzymes in the body, reduce the nitrates (NO3) found in food into nitrites (NO-2) and many foods and

preservatives contain nitrates. GSK scientists knew or should have known that human physiology and diet would lead to the development of NDMA in the human body after ingestion of ranitidine.

18. Due in large part to GSK's marketing strategy, Zantac was a wildly successful drug reaching $1 billion in total sales in December 1986. As one 1996 article put it, Zantac became the " the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that . . . enabled the product to dominate the acid/peptic marketplace." [1] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

19. Zantac became available without a prescription in 1996 and generic versions of the drug (ranitidine) became available the following year. Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top ten antacid tablet brands in the United States with sales of Zantac 150 totaling $128.9 million.

20. On September 13, 2019, in response to a citizen's petition filed by Valisure, Inc. (discussed in detail below), U.S. and European regulators stated that they are reviewing the safety of ranitidine.

21. 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.

22. 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. CVS has been followed by Walmart, Inc., Walgreens Boot Alliance, and Rite Aid Corp. to also remove Zantac and ranitidine products.

23. 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.

24. On November 1, 2019, the FDA released its preliminary results showing unsafe levels of NDMA in various ranitidine products including the brand name products controlled by Sanofi.

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[1] Wright, R., *How Zantac Became the Best-Selling Drug in History*, 1 J. HEALTHCARE MARKETING 4, 24 (Winter 1996).

25. Since November 2019, multiple manufacturers of ranitidine products have issued voluntary recalls due to findings of elevated NDMA in their product.

26. Prior to the recalls, and even in conjunction with the recalls, 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) without prior FDA approval pursuant to the mechanisms within the regulatory standards. Had any Defendant attempted to add a NDMA warning to the Zantac label (either for prescription or OTC) the FDA would not have rejected it.

V. DANGERS OF NDMA

27. According to the Environmental Protection Agency's Technical Fact Sheet, 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."[2] NDMA is no longer produced or commercially used in the United States, except for research, such as a tumor initiator in certain animal bioassays. In other words, it is only a poison.

28. Both the environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen. The World Health Organization ("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.

29. 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.

30. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure – Valsartan, Losartan, and

[2] Jane Brody, *Bottoms Up: Alcohol in moderation 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 methylating agents*, 405 MUTAT. RESEAR. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

Irbesartan – because the medications contained nitrosamine impurities that do no meet the FDA's safety standards. The FDA has established a permissible daily intake limit for the probable human carcinogen, NDMA, of 96 ng (nanogram). However, the highest level of NDMA detected by the FDA in any of the Valsartan tablets was 20.19 μg (or 20,190 ng) per tablet. In the case of Valsartan, the NDMA was an impurity caused by a manufacturing defect, and thus NDMA was present in only *some* products containing Valsartan. Based on the amount of NDMA in a single Zantac tablet, Zantac poses a greater safety risk 124 times greater than any of the recently recalled Valsartan tablets. Not only is NDMA a byproduct of the ranitidine molecule, itself, but the levels observed in recent testing show NDMA levels in excess of 3,000,000 ng.

31. 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.

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

33. 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.

34. In addition, 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).

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

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

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

38. Pursuant to the EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[3]

39. 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. And, 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).

40. 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.[4] In a similar 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.[5]

41. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.[6]

42. 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.[7]

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[3] *See* https://www3.epa.gov/airtoxics/cancer guidelines final 3-25-05.pdf.

[4] 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).

[5] La Vecchia, *et al*., *Nitrosamine intake and gastric cancer risk*, 4 EUROP. J. CANCER. PREV. 469–474 (1995).

[6] Rogers, *et al*., *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer*, 5 CANCER EPIDEMIOL. BIOMARKERS PREV. 29–36 (1995).

[7] 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)

43. 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.[8]

44. 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.[9]

45. 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.[10]

VI. HOW RANITIDINE TRANSFORMS INTO NDMA WITHIN THE BODY

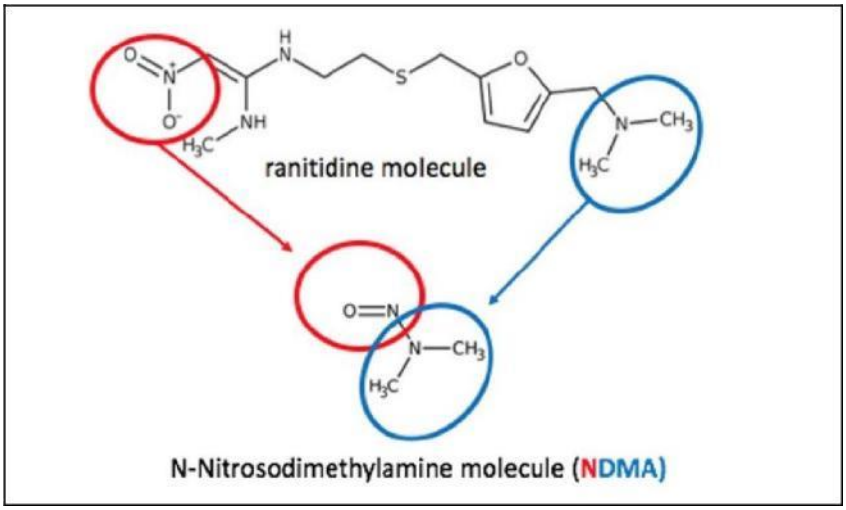
46. The high levels of NDMA produced by Zantac are not caused by a manufacturing defect but are inherent to the molecular structure of ranitidine, the active ingredient in Zantac. The ranitidine molecule contains both a nitrite and DMA group which are well known to combine to form NDMA. *See* Fig. 1. Thus, ranitidine produces NDMA by "react[ing] with itself," which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.

[8] Straif, *et al.*, *Exposure to high concentrations of nitrosamines and cancer mortalityamong a cohort of rubber workers*, 57 OCCUP ENVIRON MED 180–187 (2000).

[9] 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).

[10] 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 J NUTR. 6, 1109–1117 (2014).

Figure 1 - Ranitidine Structure & Formation of NDMA



47. 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.[11] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[12]

48. In 1981, the very year Zantac was launched commercially outside of the US, 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.

49. Dr. Silvio de Flora, an Italian researcher from the University of Genoa, wrote about experiments he had conducted looking at 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[.]"[13] 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

[11] 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).
[12] Mitch, et al., N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review, 20 ENV. ENG. SCI. 5, 389-404 (2003).
[13] De Flora, Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives, THE LANCET 993-994 (Oct. 31, 1981).

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 ascorbid acid."

50. GSL responded to Dr. de Flora's concern.[14] 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." GSK was fully aware of the potential NDMA issue, and acknowledged that when ranitidine was 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 human 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[.]"

51. In 1983, the same year Zantac was approved in the U.S., seven researchers from the University of Genoa published a study discussing the nitrosation of ranitidine and its genotoxic effects (ability to harm DNA).[15] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells. ... These findings are consistent with those of De Flora, who showed that preincubation of ranitidine with excess nitrite in human gastric juice resulted in mutagenic effects[.]"

52. Then, again in 1983, Dr. de Flora, along with four other researchers, published the complete findings.[16] 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 . . .Ascorbic acid has been proposed as an inhibitor of nitrosation combined with notrosatiable drugs and appears to block efficiently the formation of mutagenic derivatives from . . . ranitidine." *Id.*

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[14] Brittain, *et al*., *The Safety of Ranitidine*, THE LANCET 1119 (Nov. 14, 1981).
[15] Maura, et al., DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells, 18 TOX. LTTRS. 97-102 (1983).
[16] De Flora, *et al*., *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).

53. 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.[17] 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.

54. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile 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 are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

55. Valisure, LLC is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory. 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 FY19-005-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.[18] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

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[17] Le Roux, *et al*., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012).

[18] US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY19-005-DPA-S.*

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

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. So, Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

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.

60. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, *etc*.[19]

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

Table 2 – Valisure Biologically relevant tests for NDMA formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
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

62. 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. By comparison, as NDMA is found in cigarettes, 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).

63. 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

[19] *See, e.g.*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSUlEg; https://youtu.be/qvh9gyWqQns.

with ranitidine in the original approval of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

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

65. 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 by-product created is 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.

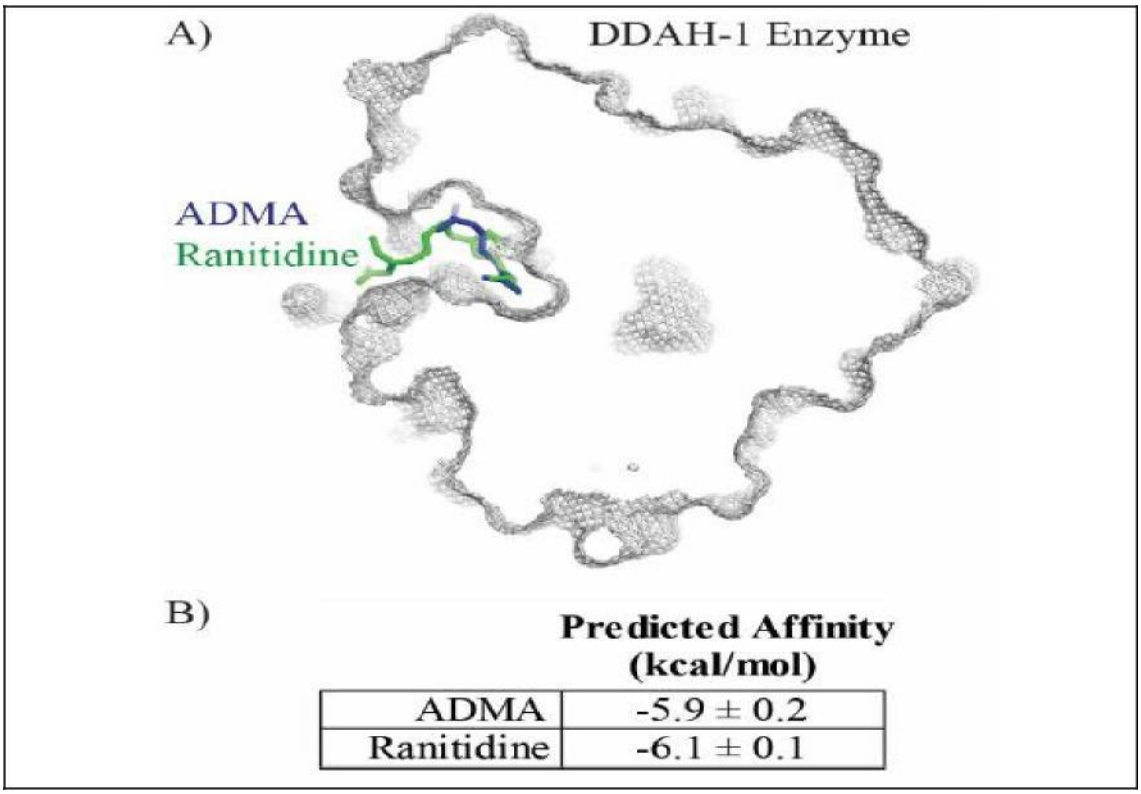
66. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach. 69. 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]."[20]

67. In Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner

[20] 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).

similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

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

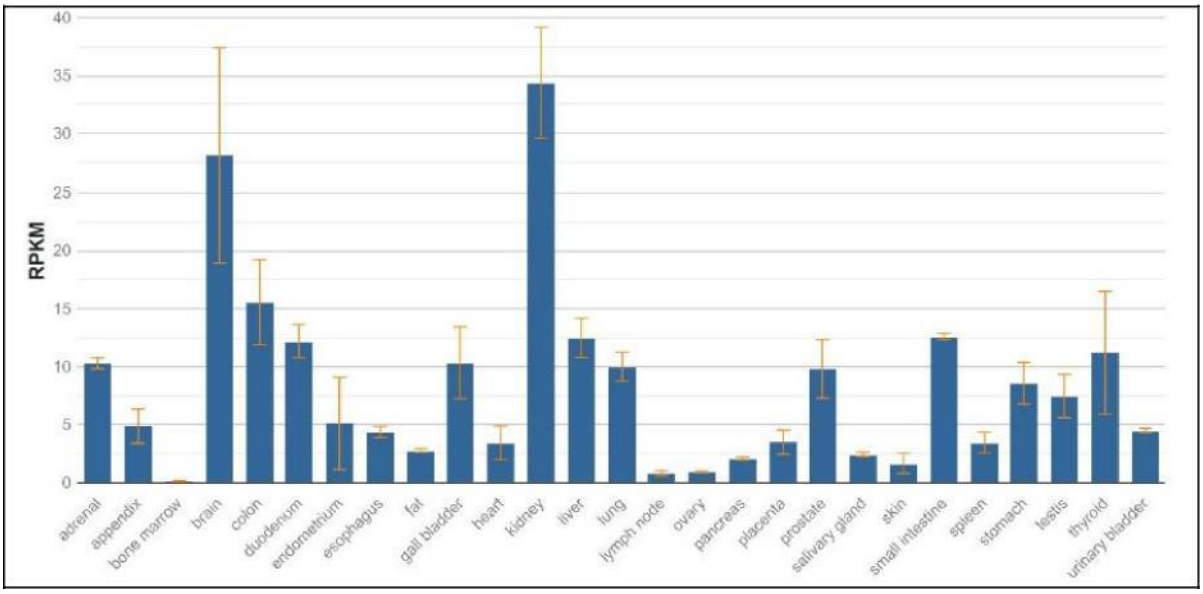


	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

68. 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.

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

Figure 3 - Expression Levels of DDAH-1 Enzyme by Organ



70. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, 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.

71. In addition to the aforementioned *in vitro* studies that suggest a strong connection between ranitidine and NDMA formation, *in vivo* clinical studies in living animals add further weight to concern over this action and overall potential carcinogenicity. A study published in the journal *Carcinogenesis* in 1983 titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite. The authors of this study concluded: "Our experimental findings have shown that simultaneous oral administration in rats of high doses of ranitidine and NaNO2 [nitrite] can produce DNA fragmentation either in liver or in gastric mucosa. [21]

[21] Brambilla, et al., Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite, 4 CARCINOGENESIS 10, 1281-1285 (1983).

72. The human data, although limited at this point, is even more concerning. A study completed and published in 2016 by Stanford University observed that healthy individuals, both male and female, who ingested Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 47,000 ng) in the proceeding 24 hours after ingestion.[22]

73. Likely due to the perceived high safety profile of ranitidine, very few epidemiological studies have been conducted on this drug.

74. A 2004 study published by the National Cancer Institute investigated 414 cases of peptic ulcer disease reported in 1986 and followed the individual cases for 14 years.[23] One of the variables investigated by the authors was the patients' consumption of a prescription antacid, either Tagamet (cimetidine) or Zantac (ranitidine). The authors concluded that "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers." Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk." NDMA is among the most common of the N-Nitrosamines.

75. A 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, no effect was observed for cimetidine administered with nitrite, but ranitidine administered with nitrine in a significant DNA fragmentation.[24]

76. Investigators at Memorial Sloan Kettering Cancer Center are actively studying ranitidine to evaluate the extent of the public health implications of these findings. Regarding ranitidine, one of the investigators commented: "A potential link between NDMA and ranitidine

[22] Zeng, et al., Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine, 37 CARCINOGENESIS 625-634 (2016).
[23] Michaud, et al., Peptic ulcer disease and the risk of bladder cancer in a prospective study of male health professionals, 13 CANCER EPIDEMIOL BIOMARKERS PREV. 2, 250254 (2004).
[24] Brambilla, *et al*., *Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance*, 52 CHEMICAL CARCINOGENESIS (1982).

is concerning, particularly considering the widespread use of this medication. Given the known carcinogenic potential of NDMA, this finding may have significant public health implications[.]"[25]

VII. DEFENDANTS HAD KNOWLEDGE OF THE NDMA DEFECT BUT FAILED TO WARN OR TEST

77. During the time that Defendants manufactured and sold Zantac in the United States, the weight of scientific evidence showed that Zantac 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.

78. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested. This was known or should have been known by Defendants.

79. 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.

80. 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.

81. "The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro

[25] Valisure Citizen Petition, *see* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf

studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product." 21 C.F.R. § 314.81(b)(2)(v).

82. Defendants ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Zantac.

83. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

84. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[26] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiff believe this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product.

85. 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. The Defendants were aware of this as GSK specifically responded to the note and attempted to discredit it. Notwithstanding this legal risk, GSK intentionally did not test for this alarming cancer risk.

86. 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.[27] 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

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[26] 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).

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." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this test was intentional and designed to mask any potential cancer risk.

87. 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 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.

VIII. PLAINTIFF-SPECIFIC ALLEGATIONS

88. Plaintiff began using brand name Zantac in 2014 and continued to use it through 2019. He took the pill five times per week for treatment of heartburn.

89. In October 2019, Plaintiff was diagnosed with bladder cancer.

90. Based on prevailing scientific evidence, exposure to Zantac (and the attendant NDMA) can cause bladder cancer in humans.

91. Plaintiff's cancer was caused by ingestion of Zantac.

92. Had any Defendant warned Plaintiff that Zantac could lead to exposure to NDMA or, in turn, cancer, Plaintiff would not have taken Zantac.

93. Plaintiff did not learn of the link between cancer and Zantac exposure until September 2019, when he learned that Zantac contained high levels of NDMA in a news article.

COUNT I
NEGLIGENCE

94. Defendants, at all pertinent times, had a duty to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use of Zantac.

95. Defendants, at all pertinent times, knew or in the exercise of reasonable care should have known, that Zantac was of such a nature that they were not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure users.

96. Defendants, at all pertinent times, had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Zantac products. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Zantac and appropriate, complete, and accurate warnings concerning the potential adverse effects of Zantac and, in particular, its ability to transform into the carcinogenic compound NDMA.

97. Defendants knew, or should have known in the exercise of reasonable care, of the hazards and dangers of Zantac and, specifically, the carcinogenic properties of NDMA when Zantac is ingested, and, in failing to disclose that risk to Plaintiff, acted in conscious disregard for the safety of Plaintiff.

98. Defendants breached that by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of Zantac, in that 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 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. Indeed, Defendants deliberately refused to test Zantac products because they knew that the chemical posed serious health risks to humans.

99. Defendants breached their duty in the sale of Zantac, including, but not limited to, the following ways:

a. Failing to manufacture, promote, formulate, create, develop, design, sell and/or distribute Zantac products without thorough and adequate pre- and post-marketing testing;

b. Negligently or intentionally concealing or failing to disclose the results of trials, tests and studies of Zantac and the carcinogenic potential of NDMA;

c. Failing to properly study and conduct the necessary tests to determine the adequacy and effectiveness of Zantac products, and whether they were safe for human consumption;

d. Failing to inform the ultimate user, Plaintiff, of all serious and relevant risks associated with Zantac, including its carcinogenic potential;

e. Failing to provide adequate instructions, guidelines, and safety precautions reasonably foreseeable with use of Zantac products;

f. Failing to warn Plaintiff, consumers, and the general public that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

g. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Zantac products;

h. Representing that their Zantac products were safe for their intended use when, in fact, Defend-ants knew or should have known the products were not safe for their intended purpose;

i. Declining to make or propose any changes to Zantac products' labeling or other promotional materials that would alert consumers and the general public of the risks of Zantac;

j. Advertising, marketing, and recommending the use of the Zantac products, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to Zantac;

k. Continuing to disseminate information to their consumers, which indicate or imply that Defend-ants' Zantac products are not unsafe for regular consumer use; and

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

100. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of Zantac.

101. Defendants, at all pertinent times, knew or in the exercise of reasonable care should have known Zantac was unreasonably dangerous and defective when put to its reasonably foreseeable use.

102. As a direct and proximate result of Defendants' negligence, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT II
STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN

103. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

104. Defendants, at all times pertinent, were responsible for designing, developing, manufacturing, assembling, marketing, testing, packaging, labeling, promoting, selling and distributing Zantac in the regular course of business.

105. Zantac is defective and unreasonably dangerous to consumers when used in a manner instructed and provided by Defendants, due to its potential to transform into the carcinogenic compound NDMA.

106. Zantac is defective and unreasonably dangerous as its utility, the does not outweigh the danger of developing cancer. Zantac is also defective in its design and/or formulation, as it is not reasonably fit, suitable or safe for its intended purpose, and the foreseeable risk of developing cancer exceed the benefits associated with its use.

107. Defendants, at all pertinent times, knew, or should have known in the exercise of reasonable care, of the hazards and dangers of Zantac and, specifically, the carcinogenic properties of NDMA when Zantac is ingested, and, in failing to disclose that risk to Plaintiff, acted in conscious disregard for the safety of Plaintiff.

108. Defendants, at all pertinent times, designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Zantac in the stream of commerce, in a defective and unreasonably dangerous condition in ways which include, but are not limited to the following:

a. Placing inadequate warnings on Zantac when it was first introduced into the stream of commerce regarding the dangers of NDMA and cancer;
b. Failing to sufficiently test, investigate, or study their Zantac products and, specifically, the ability for Zantac to transform into the carcinogenic compound NDMA within the human body;
c. Defendants knew or should have known at the time of marketing Zantac products that exposure to Zantac could result in cancer and other severe illnesses and injuries;

d. Placing a product into the stream of commerce that was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;
e. Placing a product into the stream of commerce, that was unreasonably dangerous in that it was hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;
f. Placing a product into the stream of commerce that was unreasonably dangerous and not reasonably safe when used in a reasonably anticipated or intended manner;
g. Failing to conduct adequate post-marketing surveillance of their Zantac products; and
h. Failing to employ safer alternative designs and formulations.

109. Plaintiff used and was exposed to Defendants' Zantac without knowledge of its dangerous characteristics.

110. At all pertinent times, there were practical and feasible alternative designs, for example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

111. At all pertinent times, the Zantac was substantially in the same condition as when it left the possession of Defendants.

112. At all pertinent times, Plaintiff used Zantac in a way which was reasonably foreseeable and normally intended uses by Defendants, as Defendants gave no warning in opposition.

113. As a direct and proximate result of Defendants' defective design, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

114. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems

associated with Zantac products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

115. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

116. Defendants, at all times pertinent, were engaged in the business of designing, developing, manufacturing, assembling, marketing, testing, packaging, labeling, promoting, selling and distributing Zantac in the regular course of business.

117. Defendants, at all times pertinent, researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Zantac products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Zantac products.

118. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Zantac products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of

dangers associated with Zantac. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

119. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Zantac 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.

120. 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 Zantac and the potential for ingested Zantac to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of Zantac products.

121. Defendants' Zantac products, at all times pertinent, reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in their defective condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

122. Defendants failed to warn of the reasonably foreseeable and knowable danger of Zantac products to transform into the carcinogenic compound NDMA within the human body.

123. Defendants knew or should have known that the minimal warnings disseminated with their Zantac products were inadequate, failed to communicate adequate in-formation 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.

124. This alleged failure to warn is not limited to the information contained on Zantac's labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Zantac 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.

125. Plaintiff was exposed to Defendants' Zantac products without knowledge of their dangerous characteristics.

126. Plaintiff, at all times pertinent, used Defendants' Zantac products for their intended or reasonably foreseeable purpose, without knowledge of their dangerous characteristics.

127. Plaintiff could not have reasonably discovered the defects and risks associated with Zantac products prior to or at the time of Plaintiff consuming Zantac. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

128. As a direct and proximate result of Defendants' failure to warn, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

129. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Zantac products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT IV
BREACH OF EXPRESS WARRANTY

130. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

131. Defendants, at all times pertinent, engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Zantac products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

132. Defendants expressly warranted, through direct-to-consumer marketing, advertising and labels, that the Zantac products were safe and effective for all reasonably foreseeable uses. 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 Zantac. Defendants knew and/or should have known that the risks expressly included in Zantac 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 Zantac products were safe and effective, that they were safe and effective for use by individuals such as the Plaintiff, and/or that they were safe and effective as consumer medication.

133. Plaintiff saw these advertisements, including television commercials, and believed the Zantac products were safe and effective.

134. The Defendants' Zantac products did not conform to these express representations in violation of Rhode Island General Laws §6A-2-313, as well as Rhode Island common law, because among other things, Zantac 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. Representing through their labeling, advertising, and marketing materials that Zantac products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Zantac and by expressly limiting the risks associated with use within their warnings and labels; and

b. Representing that Zantac products were safe for use and intentionally concealed information that demonstrated that Zantac, by transforming into NDMA once ingested, had carcinogenic properties.

135. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT V
BREACH OF IMPLIED WARRANTY

136. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

137. Defendants, at all times pertinent, engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Zantac products, which

are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

138. Defendants, at all times pertinent, impliedly warranted to their consumers, including Plaintiff, that Zantac products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

139. Defendants, at all times pertinent, were aware that consumers and users of their products, including Plaintiff, would use Zantac products as marketed by Defendants.

140. The Zantac products were defective in design and manufacture and were therefore not fit for their intended uses, and, were not designed, manufactured, or sold in accordance with industry standards. The Zantac products were not fit for the common, ordinary and intended uses. Therefore, Defendants breached the implied warranty of merchantability as well as the implied warrant of fitness for a particular purpose as stated in Rhode Island General Laws § 6A-2-314, and Rhode Island common law.

141. When the Zantac products entered the stream of commerce, they were unsafe for their intended use, not of merchantable quality as warranted by Defendants.

142. In reliance upon Defendants' implied warranty, Plaintiff used Zantac as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

143. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT VI
FRAUD

144. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

145. Defendants, at all times pertinent, engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Zantac products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce.

146. Defendants knew or should have known that Plaintiff, based off Defendants' representations that the Zantac medications were safe and effective as consumer medication, would purchase and ingest the Zantac products.

147. Defendants intentionally, willfully and/or recklessly concealed information concerning the dangerous nature of Zantac and the potential for ingested Zantac to transform into the carcinogenic NDMA compound, and further, made false and/or misleading statements concerning the safety of Zantac products.

148. Defendants misrepresented or concealed material facts concerning the Zantac products to consumers, including Plaintiff, with knowledge of the falsity of their misrepresentations.

149. 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, even though those risks were not readily apparent to ordinary users.

150. The misrepresentations and concealments by Defendants concerning the Zantac products include, but are not limited to:

a. Knowingly misrepresenting to Plaintiff, and the general public, through the advertisements and marketing described above, that the Zantac products are safe when used as directed;

b. Intentionally failing to disclose that when ingested, Zantac can transform into the carcinogenic NDMA compound;

c. Intentionally failing to include adequate warnings with the Zantac products regarding the potential and actual risk of the drug, as well as the nature, scope and severity of any serious injuries, including cancer; and

d. Knowingly concealing the Zantac products' carcinogenic nature and falsely marketing, labeling and advertising the products as safe for public consumption and use.

151. Plaintiff was induced to, and relied upon, Defendants' misrepresentations of material fact, and purchased and ingested the Zantac Products.

152. As a direct and proximate result of Defendants' fraudulent misrepresentation and concealment of material fact, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT VII
NEGLIGENT MISREPRESENTATION

153. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

154. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that the Zantac products were tested and found to be safe and effective. Defendants' representations, however, were false.

155. Defendants failed to exercise ordinary care in the representations concerning the Zantac products while they were involved in their manufacture, sale, testing, quality control and assurance, and distribution into interstate commerce, because they negligently misrepresented the Zantac products high risk of unreasonable, dangerous and adverse side effects.

156. Defendants breached their duty in representing that the Zantac products have no serious and life-threatening side effects, and were safe for all their intended uses.

157. As a foreseeable, direct and proximate result of this negligent misrepresentation, Defendants had reason to know that the Zantac products had been insufficiently tested, they lacked adequate and accurate warnings, and they created a higher and/or higher than acceptable risk of adverse effects, like cancer.

158. At all pertinent times, the misrepresentations, omissions and concealments concerning the Zantac products made by Defendants include, but are not limited to:

a. Failing to disclose to Plaintiff, and those similarly situated, through adequate warnings, representations, labeling or otherwise, that the Zantac products were inherently dangerous and carcinogenic in nature, posing serious health risk to consumers;

b. Failing to disclose to Plaintiff, and those similarly situated, through adequate warnings, representations, labeling or otherwise, the material fact that use of the Products increased the risk of cancer; and

c. Falsely marketing, advertising, labeling and selling the Zantac products as safe and effective for public consumption, despite knowledge of its carcinogenic nature.

159. Defendants, at all times pertinent, failed to exercise reasonable care in ascertaining or sharing information regarding the Zantac products' safe use, failed to disclose facts indicate that Zantac products were inherently dangerous and carcinogenic in nature, and otherwise failed to exercise reasonable care in communicating this information to Plaintiff.

160. Plaintiff, at all times pertinent, was neither aware of the falsity of the foregoing misrepresentations, nor that the material facts concerning the Zantac products had been concealed or omitted. In reasonable reliance on Defendants' omissions and/or misrepresentations, Plaintiff was induced to and did purchase and use the Zantac products. If Defendants had disclosed true and accurate material facts concerning the risks of the Zantac products, in particular the risk of developing cancer, the Plaintiff would not have purchased and used the Zantac products.

161. Plaintiff's reliance upon Defendants misrepresentations and omissions was justified and reasonable because, among other reasons, those misrepresentations and omissions were made by individuals and entities who were in a position to know the material facts concerning the Zantac products and the association between the Zantac products and cancer. Plaintiff was not in a position to know these material facts, and Defendants failed to warn or otherwise provide notice as to those risks, thereby inducing Plaintiff to use the Zantac products.

162. As a direct and proximate result of Defendants' negligent misrepresentation and concealment of material fact, Plaintiff purchased and used Zantac products, causing him to develop cancer, incur medical bills, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT VIII
PUNITIVE DAMAGES

163. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length therein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of Plaintiff's resident State.

164. Defendants sold the Zantac products to Plaintiff and other consumers throughout the United States without doing adequate testing to ensure that the Zantac products were reasonably safe for their intended use.

165. Defendants sold the Zantac products to Plaintiff and other consumers throughout the United States in spite of their knowledge that the Zantac products cause the problems heretofore set forth in this Complaint, thereby causing the severe and debilitating injuries suffered by the Plaintiff.

166. At all times pertinent hereto, Defendants knew or should have known that the Zantac products were inherently dangerous with respect risk of cancer, loss of life's enjoyment, an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

167. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Zantac products, including but not limited to information regarding the increased risk of developing cancer.

168. Defendants' misrepresentations included knowingly withholding material information from the consumers, including Plaintiff, concerning the safety and efficacy of the Zantac products.

169. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Zantac products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products.

170. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Zantac products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and recklessly failed to advise the public of the same.

171. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Zantac products.

172. Notwithstanding the foregoing, Defendants continue to aggressively market the Zantac products to consumers, without disclosing the true risk of side effects.

173. Defendants knew that the Zantac products were defective and of an unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Zantac products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the Zantac products.

174. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Zantac products in order to ensure continued and increased sales.

175. Defendants' intentional, reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Zantac products against their benefits.

176. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiffs and other members of the public will in the future be required to obtain further medical care and/or hospital care and medical services.

177. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles and the statutory provisions of the Plaintiff's respective home state and Defendants' home states.

178. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

TAG-ALONG ACTION

179. This is a potential tag-along action and in accordance with 28 U.S.C. §14-7, it should be transferred to the United States District Court for Florida Southern District of Florida for inclusion in *In Re: Zantac (Ranitidine) Products Liability Litigation*, MDL 2924 (Hon. Robin L. Rosenburg).

RELIEF REQUESTED

WHEREFORE Plaintiff prays for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Mr. Lane, as follows:

1. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

2. for compensatory damages according to proof;

3. for declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Defendants' wrongdoing to Mr. Lane;

4. for disgorgement of profits;

5. for an award of attorneys' fees and costs;

6. for prejudgment interest and the costs of suit;

7. punitive or exemplary damages according to proof; and

8. for such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: February 28, 2020

RESPECTFULLY SUBMITTED,

/s/ Vincent Greene

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