UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION	**MDL NO. 2924** **20-MD-2924** **JUDGE ROBIN L. ROSENBERG** **MAGISTRATE JUDGE BRUCE E. REINHART**
CHRISTOPHER MONTGOMERY, **Plaintiff,** **v.** **SANOFI S.A., SANOFI-AVENTIS US LLC, SANOFI US SERVICES INC, CHATTEM, INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., GLAXOSMITHKLINE, LLC, GLAXOSMITHKLINE, PLC, and PFIZER, INC.,** **Defendants.**	**Case No. _____** **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, by and through undersigned counsel, hereby brings this Complaint for damages against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi S.A., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants"); Pfizer, Inc. ("Pfizer"); GlaxoSmithKline, LLC and GlaxoSmithKline, PLC (collectively "GSK" or "GSK Defendants"); and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), and alleges the following based on personal knowledge, the investigation of counsel, and information and belief:

NATURE OF THE ACTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or

sale of the drug Zantac (also known generically as ranitidine). Plaintiff maintains that Zantac is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

2. Zantac was one of the first global blockbuster drugs, reaching annual sales of $1 billion by 1987.[1] For more than a decade after its 1983 market debut, it was one of the all-time, best-selling prescription drugs. Even today, after the introduction of generic alternatives, Zantac still ranks among the top 100 best-selling prescription drugs in the United States, with more than 15,000,000 prescriptions written for Zantac in 2016 alone.[2]

3. Recent revelations by independent researchers have uncovered what will likely go down as one of the gravest public-health frauds in modern times. Put simply, Zantac is a cancerous poison. When ingested, every tablet (and every dose), produces the toxic carcinogen N-nitrosodimethylamine ("NDMA") in the body. NDMA is a by-product or waste product of various industrial processes, including the manufacture of rocket fuel. NDMA's lone medical use is to cause cancer in animals for laboratory experimentation. NDMA became notorious as the poison of choice in two sensational murders in the U.S. and Germany.[3] Cigarette smoking in most public places in the United States has been banned, in part, because it produces NDMA, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."[4]

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[1] Richard Wright, M.D., *How Zantac Became the Best-Selling Drug in History*, 16(4) J. HEALTHCARE MARKETING 24 (Winter 1996).
[2] ClinCalc.com, Ranitidine, ClinCalc DrugStats Database, available at https://clincalc.com/DrugStats/Drugs/Ranitidine (last accessed Nov. 11, 2019).
[3] Chase Purdy, *A Common Blood-Pressure Medicine is Being Recalled Because of a Toxic Ingredient*, available at https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressuredrug- because-it-was-mixed-with-ndma/ (last accessed Nov. 21, 2019).
[4] U.S. ENVIRONMENTAL PROTECTION AGENCY, Technical Fact Sheet – N-Nitroso-dimethylamine

4. Once present in the body, NDMA further metabolizes into other known carcinogens, including formaldehyde. In short, Zantac is a cancerous poison that at all times was sold by Defendants that knew, or had reason to know, it was a cancerous poison.

INTRODUCTION

5. Recently, the public has been inundated with reports of serious impurities in pharmaceutical drugs. In 2019 alone, the U.S. Food and Drug Administration announced the largest generic pharmaceutical recall in U.S. history, of blood pressure medications such as valsartan and other angiotensin receptor blockers ("ARB") that contained dangerous levels of NDMA.[5] The NDMA in valsartan resulted from unlawful manufacturing processes. This case challenges a deeper wrong because NDMA is inherent in Zantac, even if it is perfectly manufactured.

6. Since 1983, Zantac—the brand-name version of the generic drug ranitidine—has been used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.[6] Before Zantac, the acid-reflux market was dominated by Tagamet. GSK (then Glaxo Holdings) was a relatively unknown British pharmaceutical company. Then came the development by John Bradshaw of Zantac and the ruthless promotion of the drug in the U.S. market, which was accomplished through a marketing alliance with Hoffman-La Roche.

(NDMA), available at https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf (last accessed Nov. 21, 2019).

[5] U.S. FOOD & DRUG ADMIN., *FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity* (July 13, 2018), available at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (last accessed Nov. 21, 2019).

[6] Ranitidine hydrochloride – Drug Summary, PRESCRIBER'S DIGITAL REFERENCE, available at https://www.pdr.net/drug-summary/Zantac-150-and-300-Tablets-ranitidine-hydrochloride-241.3325 (last accessed Nov. 21, 2019).

Under the arrangement, Zantac was sold under the GSK name and Hoffman-La Roche received a royalty on sales. Hoffman-La Roche dispatched a salesforce of more than 1,000 people and captured 25% of the antiulcer market in just over six months. Within three years, sales of Zantac had surpassed Tagamet, and by 1989, accounted for 53% of the antiulcer market. Zantac catapulted GSK into a market-leading position as one of the largest pharmaceutical companies in the world.

7. GSK and Hoffman-La Roche's unprecedented success was made possible through a fraudulent scheme conceived by Glaxo, which perpetrated and perpetuated the scheme along with Pfizer, Boehringer, and Sanofi, beginning with Zantac's U.S. debut in 1983. At all times that Defendants sold Zantac, each one knew or had reason to know that the drug had (and has) an inherent, unreasonably dangerous, cancer-causing defect. When ingested, Zantac produces high quantities of NDMA, a chemical the World Health Organization has described as "clearly carcinogenic."[7]

8. The dangers of NDMA were already well-known when GSK and Hoffman-La Roche launched their aggressive marketing effort that made Zantac the best-selling drug in the world. So, too, were the risks that Zantac would create NDMA when ingested. At the time when GSK researchers were desperately looking for an alternative to Tagamet, existing scientific literature strongly suggesting that drugs like ranitidine, which contain a dimethylamine (DMA) group, are highly likely to form NDMA when combined with substances found in the body, such as nitrites. GSK knew of those studies and attempted to discredit and paper them over with its own flawed, pre-textual studies, all in service of the main goal—to launch an all-out assault on the

[7] R.G. Liteplo, et al., *Concise International Chemical Assessment Document 38: N-itrosodimethylamine, WORLD HEALTH ORGANIZATION* (2002), available at https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

lucrative antiulcer market, take it over, and catapult GSK into the top ranks of the international pharmaceutical world.

9. Perhaps the most comprehensive study of Zantac recently presented is the work of independent research firms Valisure LLC and ValisureRX LLC (collectively "Valisure"). A few months ago, they revealed that they had "detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products," including Zantac.[8]

10. The tests conducted by Valisure show that "ranitidine can react with itself in standard analysis conditions . . . at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen."[9] Valisure tests detected 2,511,469 ng of NDMA per 150 mg tablet of Zantac—more than 26,000 times greater than the amount that can be safely ingested daily.[10] When Valisure conducted tests with conditions simulating the human stomach, the amount of NDMA peaked at 304,500 ng per tablet—3,171 times more than the amount that can be safely ingested daily.[11]

11. This staggering amount of NDMA is found in every tablet of Zantac. A typical consumer with peptic ulcer disease taking Zantac for a typical treatment period of eight weeks is exposed to more than 280,000,000 ng (0.28 grams) of NDMA. A consumer who takes a 150 mg maintenance dose of Zantac once daily is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year.

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[8] Valisure Citizen Petition to FDA at 6 (Sept. 9, 2019), available at https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf ("Citizen Petition") (last accessed Nov. 21, 2019).
[9] *Id.* at 2.
[10] *Id.* at 6–7.
[11] *Id.*

12. Valisure notified the FDA of its findings by filing a Citizen Petition on September 13, 2019. In addition, Valisure submitted a copy of its Citizen Petition to the World Health Organization ("WHO") and the International Agency for the Research of Cancer ("IARC") for inclusion in IARC Monographs on the Valuation of Carcinogenic Risks to Humans, and requested that ranitidine be classified as a human carcinogen.

13. In addition to testing Zantac for NDMA, Valisure also tested several other alternative drugs to Zantac, to determine if they also contained NDMA. The drugs tested included Pepcid, Prilosec, Nexium, Prevacid, Protonix, AcipHex, and Dexilant. Valisure did not detect any NDMA in any of these drugs.[12]

14. Zantac is taken not only by adults but also is given to children and teenagers to treat gastroesophageal reflux disease, among other things. Further, Zantac often is used by pregnant women to treat pregnancy-related heartburn symptoms—exposing both the pregnant woman and her developing fetus to NDMA, which is not only carcinogenic and toxic, but also DNA-damaging.

15. On September 13, 2019, when the news broke that Zantac exposed consumers to NDMA, "[g]lobal health regulators sounded a coordinated alarm."[13] In response, and as further set forth below, most countries have pulled Zantac and generic ranitidine from the market. In the U.S., many pharmacies and ranitidine manufacturers themselves (including Defendants GSK and Sanofi) have pulled Zantac from their shelves or recalled their ranitidine products.

16. Unfortunately, thus far, the FDA has done very little to protect the American people from Zantac, and its messaging has been contradictory, confusing, and slow. Valisure first notified

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[12] *Id.* at 15-16.

[13] BLOOMBERG LAW, *Carcinogen in Zantac and Generics Triggers FDA*, EU Probes (2) (Sept. 13, 2019), available at https://news.bloomberglaw.com/health-law-and-business/fda-eu-probingcarcinogen-detected-in-versions-of-zantac-1 (last accessed Nov. 1, 2019).

the FDA in June 2019 about the formation of NDMA from ranitidine. The FDA did nothing and made no public comments, even dismissive comments, on the issue.

17. On September 13, 2019, the FDA issued its first statement acknowledging that Zantac contains NDMA but, in what appears to have been an attempt to downplay the risk, claimed the amount of NDMA detected was low, stating that "[t]he U.S. Food and Drug Administration has learned that some ranitidine medicines, including some products commonly known as the brand-name drug Zantac, contain a nitrosamine impurity called Nnitrosodimethylamine (NDMA) at low levels."[14]

18. Further, although numerous regulators outside the United States had cautioned those taking Zantac to consider an alternative, given the availability of many safe alternatives, on September 13th, the FDA told Americans they need not stop taking OTC Zantac.[15]

19. Less than a month later, on October 2, 2019, in an apparent about-face to save face, the FDA stated that it had found "unacceptable levels of NDMA in samples of ranitidine," although it provided no details of when or how.[16] The FDA has not disclosed what those levels were, what tests it used, or any other information that might illuminate its findings and educate the public. It does seem, however, that the FDA is finally beginning to understand and admit the core fact at the heart of this complaint—when ingested, Zantac causes the body's formation of dangerous amounts of cancer-causing compounds. On October 24, 2019, an FDA spokesperson belatedly stated that

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[14] FDA, Zantac (ranitidine): *Safety Information - NDMA Found in Samples of Some Ranitidine Medicines*, available at https://www.fda.gov/safety/medical-product-safety-information/zantac-ranitidine-safety-information-ndma-found-samples-some-ranitidine-medicines safety-information-ndma-found-samples-some-ranitidine-medicines (last accessed Nov. 21, 2019).

[15] *Id.*

[16] Eric Palmer, *FDA now says impurity level in Zantac and other antacids is too high*, FiercePharma.com (Oct. 2, 2019), available at https://www.fiercepharma.com/manufacturing/fda-now-says-impurity-level-zantac-and-other-antacids-too-high too-high (last accessed Nov. 21, 2019).

the FDA is currently "working to understand what happens to NDMA levels in the body, after ranitidine has been exposed to acid in the stomach."[17]

20. At all relevant times, all Defendants knew or had reason to know that Zantac exposes users to unsafe levels of the carcinogen NDMA. During the period in which Defendants manufactured and distributed Zantac, numerous scientific studies were published proving, among other things, that ranitidine (the generic bioequivalent of Zantac) forms NDMA when placed in drinking water, and persons who consume ranitidine have a 400-fold increase of NDMA concentration in their urine. Despite the weight of scientific evidence showing that Zantac exposes people who take it to unsafe levels of the carcinogen NDMA, no defendant ever disclosed this risk to the FDA, not on the drug's label, and not by any other means. Instead, Defendants put profits ahead of safety and aggressively marketed an inherently, unreasonably dangerous drug, reaping massive profits from exposing millions of people to cancer-causing chemicals.

JURISDICTION AND VENUE

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Plaintiff is a citizen of a state different from any Defendant.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Zantac within Florida and this District, and a substantial part of the events and omissions giving rise to the claim occurred in this District.

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[17] Michael Erman, *FDA investigating whether Zantac causes carcinogens to form in users*, REUTERS (Oct. 24, 2019), available at https://www.reuters.com/article/fda-heartburn-zantac/fda-investigating-whether-zantac-causes-carcinogens-to-form-in-patients-bodies-idUKL2N2791S0 whether-zantac-causes-carcinogens-to-form-in-usersidUSKBN1X32NA (last accessed Nov. 21, 2019).

PARTIES

23. Plaintiff Christopher Montgomery is a natural person and at all relevant times a resident and citizen of Hillsborough County, Florida. Plaintiff brings this action for personal injuries sustained by the use of Zantac. Plaintiff regularly ingested Zantac for 11 years. As a direct and proximate result of ingesting Zantac, Plaintiff developed colon cancer in July of 2016.

A. GSK Defendants (1983-2009)

24. The GSK Defendants were the original innovator of the Zantac and controlled the U.S. rights and New Drug Application ("NDA") for prescription Zantac between 1983 and 2009. By controlling the Zantac NDA, they also directly controlled the labeling for all Zantac products through 2009. And, GSK's negligence and misconduct related to Zantac as an innovator directly led to the failure to warn for other OTC versions of Zantac. After 1996, GSK Defendants also sold over-the counter ("OTC") versions of Zantac and continued to sell the prescription versions of Zantac until recently.

25. At all relevant times, the GSK Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac.

26. Defendant GlaxoSmithKline, PLC is a British corporation, with a principal place of business in the United Kingdom, and the successor-in-interest to the companies that developed, patented, and commercialized the molecule know as ranitidine. Ranitidine was initially developed by Allen & Hansbury Ltd.[18] Allen & Hansburys was acquired by Glaxo Labs Ltd. When ranitidine was discovered in the late 1970s, Allen & Hansburys Ltd. was a subsidiary of Glaxo Labs Ltd. In

[18] D. Lednicer, *Chronicles of Drug Discovery*, ACS PROFESSIONAL REFERENCE BOOK. pp. 45-81 (1993).

December 1978, Allen & Hansburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office, which covered the ranitidine molecule. Glaxo Labs (now GlaxoSmithKline PLC) also conducted the clinical trials and other trials associated with the New Drug Application (NDA 18703) it submitted to the FDA for Zantac. In 1983, Glaxo Holdings Ltd. was awarded approval by the U.S. FDA to sell Zantac in the United States.

27. Defendant GlaxoSmithKline LLC is a Delaware corporation with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112 and Five Moore Drive, Research Triangle, North Carolina, 27709. GSK controlled the rights to prescription Zantac between 1983 and 2009 and either directly, or through a subsidiary, marketed prescription forms of Zantac in the United States.

28. Upon information and belief, at all relevant times, the GSK Defendants were present and doing business in the State of Florida, and transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business. The GSK Defendants expected or should have expected that their acts would have consequences within the United States of America, and the State of Florida.

D. Pfizer (1996-2005)

29. From 1996 through 1999, Warner-Lambert Co. (now a Pfizer subsidiary), owned the rights to manufacture, market, and sell OTC Zantac, and Warner-Lambert manufactured, marketed, and sold OTC Zantac throughout the United States during that period. In or around 2000, Defendant Pfizer acquired Warner-Lambert, and Warner-Lambert merged into Pfizer. From 2000 through approximately 2005, Pfizer possessed the rights to manufacture, market, and sell OTC Zantac, and Pfizer manufactured, marketed and sold OTC Zantac throughout the United States during that period through its Consumer Healthcare division.

30. Defendant Pfizer is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017.

31. Upon information and belief, at all relevant times, Pfizer was present and doing business in the State of Florida, and transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business. Pfizer expected or should have expected that its acts would have consequences within the United States of America, and the State of Florida.

B. Boehringer (2006-2017)

32. Boehringer controlled the U.S. rights to OTC Zantac from 2006 to 2017, and manufactured and distributed the drug in the United States during that period. Boehringer was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac.

33. Defendant Boehringer is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation.

34. Upon information and belief, at all relevant times, Boehringer was present and doing business in the State of Florida, and transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business. Boehringer expected or should have expected that its acts would have consequences within the United States of America, and the State of Florida.

C. Sanofi Defendants (2017-Present)

35. The Sanofi Defendants have controlled the U.S. rights and NDA to OTC Zantac from January 2017 to the present, and manufactured and distributed the drug in the United States

during that period. The Sanofi Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac.

36. Defendant, Sanofi-Aventis U.S. LLC, was and is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of Sanofi S.A. Sanofi-Aventis U.S. LLC is duly licensed to transact business in the State of Florida, and lists its registered agent as Corporation Service Company, with the address 1201 Hays Street, Tallahassee, Florida 32301.

37. Defendant, Sanofi US Services Inc., was and 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 US Services Inc. is duly licensed to transact business in the State of Florida, and lists its registered agent as Corporation Service Company, with the address 1201 Hays Street, Tallahassee, Florida 32301.

38. Defendant Sanofi S.A., also known as Sanofi Consumer Healthcare, is a French multinational pharmaceutical company headquartered in Paris, France, with its principal place of business located 54, Rue La Boétie in the 8th arrondissement. Defendant company Sanofi S.A. was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthélabo, which were each the product of several previous mergers. The Defendant company Sanofi S.A. changed its name to Sanofi in May 2011.

39. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A., through its subsidiary Chattem, Inc., exercised substantial

control over the design, testing, manufacture, packaging and/or labeling of Zantac that caused the harm to Plaintiff for which recovery is sought.

40. Upon information and belief, at all relevant times, the Sanofi Defendants were present and doing business in the State of Florida, and transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business. The Sanofi Defendants expected or should have expected that their acts would have consequences within the United States of America, and the State of Florida.

41. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and/or distribute Zantac, with full knowledge of its dangerous and defective nature.

42. The Sanofi Defendants, GSK Defendants, Pfizer and Boehringer shall collectively be referred to hereafter as "Defendants."

FACTUAL ALLEGATIONS

A. A Brief History of Zantac

43. Zantac was developed by Defendant GSK and approved for prescription use by the FDA in 1983.[19] 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.[20]

44. Due in large part to Glaxo's marketing strategy, Zantac was a tremendously successful drug, reaching $1 billion in total sales in December 1986.[21] As one 1996 article put it,

[19] Wright, *supra* footnote 1, at 26.
[20] *Histamine H2 Antagonist (Oral Route, Injection Route, Intravenous Route)*, MAYO CLINIC (last updated September 30, 2019), https://www.mayoclinic.org/drugs-supplements/histamine-h2-antagonistoral-route-injection-route-intravenous-route/description/drg-20068584.
[21] Wright, *supra* footnote 1, at 27.

Zantac became "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."[22] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[23] Indeed, Zantac has been marketed as a safe and effective treatment for infants, children, and adults.

45. Common brands of ranitidine include: Zantac, Wal-Zan 75, Heartburn Relief, Acid Reducer, Acid Control, Wal-Zan 150, Zantac Maximum Strength, and Zantac 75.

46. Zantac is available for purchase over-the-counter in 75 and 150 mg pills, and by prescription for 300 mg pills.

47. Zantac became available without a prescription in 1996,[24] and generic versions of the drug (ranitidine) became available the following year.[25] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[26] 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[27]-a 3.1% increase from the previous year.[28]

48. As stated above, over the past 20 years, the rights to Zantac in the U.S. have changed hands several times.

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[22] *Id.* at 25.
[23] *Id.* at 27.
[24] *Id.* at 28.
[25] David Ranii, *Generic Zantac on market*, NEWS AND OBSERVER (Aug. 5, 1997).
[26] *GlaxoSmithKline – Product Portfolio*, PHARMACEUTICALS COMPANY ANALYSIS (Jan. 21, 2003).
[27] *Sales growth of leading brands of antacid tablets in the United States in 2018 (change to prior sales year)*, STATISTA (last visited Nov. 21, 2019), https://www.statista.com/statistics/194547/us-salesgrowth-of-antacid-tablet-brands-in-2013/.
[28] *Id.*

49. Pfizer acquired the U.S. rights to OTC Zantac around June 2000 and manufactured and sold the drug in the United States, including in Florida, from August 2004 through December 2006.[29]

50. Defendant Boehringer acquired the U.S. rights to OTC Zantac in late 2006, and manufactured and sold the drug in the United States, including in Florida, from approximately January 2007 to January 2017.[30]

51. The Sanofi Defendants acquired the U.S. rights to OTC Zantac in approximately January 2017 and since that time have been manufacturing and selling the drug in the United States, including in Florida.[31]

52. The Sanofi Defendants currently manufacture and market the following products:

i. Zantac
ii. Zantac 150
iii. Zantac 150 Acid Reducer
iv. Zantac 150 Maximum Strength
v. Zantac Maximum Strength Cool Mint
vi. Zantac 75
vii. Zantac 75 Regular Strength
viii. Zantac Maximum Strength 150 Cool Mint
ix. Zantac (Ranitidine Injection)
x. Zantac (Ranitidine Syrup)
xi. Zantac (Ranitidine Tablets and Capsules)
xii. Zantac Cool Mint
xiii. Zantac Injection

[29] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021698s000_MedR.pdf.
[30] *See* Digesting an acquisition: Patrick Hennig, Boehringer Ingelheim; Ingelheim *Pharmaceuticals to acquire U.S. rights for Zantac product line; Interview*, DRUG STORE NEWS
(Mar. 5, 2007); Mike Pare, Chattem adds Zantac, Dulcolax to portfolio, CHATTANOOGA TIMES
FREE PRESS (TENNESSEE) (Feb. 8, 2017).
[31] *Id.*

53. Defendant GlaxoSmithKline LLC, the original innovator of Zantac, retained the prescription rights to Zantac from 1983 through 2009.

B. Defendants were aware of the dangers of N-Nitrosodimenthylamine (NDMA).

54. "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens."[32]

55. According to a publication from the National Institute of Health, "[NDMA] is a volatile, combustible, yellow, oily liquid nitrosamine with a faint characteristic odor that decomposes when exposed to light and emits toxic fumes of nitrogen oxides when heated to decomposition. NDMA is primarily used in laboratory research to induce tumors in experimental animals. This substance may be formed during the cooking of foods, especially cured meats and fish, that contain sodium nitrite as a preservative, but is also found in several vegetables, cheeses, alcoholic beverages and fruits, and as a contaminant in rubber products. Exposure to [NDMA] irritates the skin and eyes and damages the liver. NDMA is also used to create cancer in rats for cancer research.[33]

56. 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."[34] The World Health Organization (WHO) similarly reported in 2002 that "NDMA

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[32] *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)*, ENVIRONMENTAL PROTECTION AGENCY (Jan. 2014), https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf.

[33] https://cancerres.aacrjournals.org/content/canres/51/23_Part_2/6452.full.pdf (accessed Nov. 21, 2019).

[34] 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

has been consistently potently carcinogenic in all experimental species examined."[35] As a result, the WHO has recognized that "NDMA is clearly carcinogenic. There is overwhelming evidence that NDMA is mutagenic and clastogenic."[36] NDMA is no longer produced or commercially used in the United States, except for research.[37] In other words, it is only a poison.

57. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[38] 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."[39] The FDA also recognizes the danger of such compounds, setting strict daily acceptable intake limits of NDMA in pharmaceuticals of 96 ng.[40]

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because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents*, 405 MUTATION RESEARCH 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumours of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[35] Liteplo, RG, Meek ME and Windle W. N-Nitrosodimethylamine. Concise International Chemical Assessment Document 38, World Health Organization, Geneva (2002), available at https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

[36] *Id.*

[37] *Technical Fact Sheet*, *supra* footnote 32.

[38] *Id.*; World Health Organization, *N-Nitrosodimethylamine (NDMA)*, GUIDELINES FOR DRINKING-WATER QUALITY (3rd ed. 2008) [hereinafter *WHO Guidelines*], *available at* https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[39] *Id.*

[40] FDA updates table of interim limits for nitrosamine impurities in ARBs (February 28, 2019). *US Food and Drug Administration, available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

58. 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.[41]

59. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure-valsartan, losartan, and irbesartan-because the medications "contain[ed] nitrosamine impurities that don't meet the [FDA's] safety standards,"[42] which again provide that the intake of NDMA in pharmaceuticals should be no more than 96 ng.[43] 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.[44] 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.

60. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying the FDA-recommended GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan[45]—the level of NDMA in Zantac is 2,511,469 ng per Zantac tablet-124 times more than the highest amount detected in the recalled valsartan.[46]

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[41] *See, e.g.,* Karen De Witt, *Carcinogen Fear Allayed*, THE NEW YORK TIMES (July 2, 1980) (reporting recall of beer that contained higher level of nitrosamines than that permitted by FDA).
[42] *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, FDA (May 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-iireceptor-blockers-arbs-including-valsartan-losartan-and-irbesartan.
[43] *Id.*
[44] *See Laboratory analysis of valsartan products*, FDA (May 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products.
[45] *Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA)Impurity Assayby GC/MS-Headspace*, FOOD & DRUG ADMINISTRATION (Jan. 25, 2019), https://www.fda.gov/media/117843/download.
[46] *See* Citizen Petition at 5;.

61. Moreover, unlike valsartan, the high levels of NDMA produced by Zantac is not a contamination problem; rather, the problem is inherent to the molecular structure of ranitidine, the active ingredient in Zantac. In the chemical environment of the human stomach, the ranitidine molecule degrades into the known carcinogen, NDMA: "The ranitidine molecule contains both a nitrite and a dimethylamine ('DMA') group which are well known to combine to form NDMA."[47] Thus, ranitidine produces NDMA by "react[ing] with itself,"[48] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[49]

C. Defendants did not disclose to consumers that Zantac exposes users to high levels of the carcinogen NDMA, despite scientific studies alerting defendants of this fact.

62. At the time that ranitidine was developed, the existing scientific literature already strongly suggested that drugs like ranitidine, which contain a dimethylamine (DMA) group, were highly likely to form NDMA when combined with other substances found in the body, such as nitrites. For example, a person taking Zantac likely would do so in connection with a meal. Many foods and meals contain nitrates in greater amounts than the body needs. Bacteria in saliva and the stomach, or enzymes in the body, can reduce the nitrates (NO3) found in food into nitrites (NO2). Additionally, some nitrites are found naturally in food or added as a preservative. Thus, at the time of ranitidine's discovery, GSK scientists knew or had reason to know that the very events that cause one to take Zantac also put a person at risk from NDMA.

63. Further, in 1981, the year Zantac commercially launched outside of the US, two exchanges in *The Lancet*, one of which involved GSK, discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H2 blocker, has a similar chemical structure to

[47] *Combined N-Nitrosodimethylamine*, *supra* footnote 45 at 19.
[48] *Id.* at 2.
[49] *Id.* at 1, 6.

ranitidine. *The Lancet* was and is one of the most widely read and respected medical and scientific publications, and thus, GSK (and the other Defendants) had actual knowledge of these discussions about ranitidine's toxicity in 1981.

64. In one exchange, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, described how the researchers detected "mutagenic nitroso derivatives" in vitro for both cimetidine and ranitidine.[50] De Flora did recognize that his studies were in vitro, and that, as such, they were not perfectly predictive of how ranitidine would perform in humans. GSK's actual knowledge of this article at the time is proven by its specific response in *The Lancet*, which attempted to discredit de Flora's research. In its response, GSK cited its own, apparently flawed, recent study. Despite the flaws in its the study, GSK nonetheless admitted to having detected a "product" that was "mutagenic" in ranitidine, although it failed to clearly specify what that "product" was.[51]

65. In a second set of articles in *The Lancet* around the same time as the de Flora article, medical researchers from England discussed a study they performed on 140 human patients taking cimetidine (the "Reed Study"). The Reed study observed that those who took cimetidine had a much higher level of N-nitrosamines than those in a control group who did not take cimetidine.[52] In response, Roger Brimblecombe, a researcher from Smith Kline and French Research, Ltd.,

[50] S. De Flora, Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives, THE LANCET, pp. 993-994 (Oct. 31, 1981).
[51] R.T. Brittain, D.M. Harris, L.E. Martin, D. Poynter, B.J. Price, The Safety of Ranitidine, THE LANCET, p. 1119 (Nov. 14, 1981). The article notes that these researchers are from "Glaxo Group
Research Ltd." in England.
[52] P. I. Reed, K. Haines, P.L.R. Smith, F.R. House, C.L. Walters, Effect of Cimetidine on Gastric Juice N-Nitrosamine Concentration, THE LANCET (Sept. 12, 1981).

criticized the Reed Study and claimed that unnamed "extensive studies" had demonstrated no "aetiological link between cimetidine treatment and the development of gastric cancer."[53]

66. Importantly, Brimblecombe also stated that, "[t]he hypotheses raised by Reed and his colleagues are important and have been publicly and extensively discussed over the past two and half years. A great deal of research, both in our laboratories and in others, is in progress."[54] The formation of nitrosamines from cimetidine and ranitidine use was known to GSK and others at that time, and was a subject of much discussion in the scientific community.

67. Dr. Reed and his co-authors sounded the alarm on Zantac in 1981, but no one, including any of the Defendants, listened. In 1983, another study was published, this one specifically relating to ranitidine. Dr. Silvio de Flora (who had authored the 1981 piece in *The Lancet* that GSK sought to discredit), and a group of researchers from the University of Genoa published a study specifically describing the formation of N-nitrosamines from ranitidine and an excess of nitrite under certain conditions.[55] On information and belief, GSK and the other Defendants knew or had reason to know of this study.

68. Further, another 1983 article specifically identified and discussed the toxicity of ranitidine. Another group of researchers from the University of Genoa demonstrated that *in vitro*, and under certain conditions, ranitidine has a tendency to form DNA-damaging nitroso compounds (like NDMA).[56] Although the study was performed on hamsters, and used conditions not

[53] Roger Brimblecombe, Cimetidine, Nitrosation, and Carcinogenicity, THE LANCET, pp. 686-687 (Sep. 26, 1981).
[54] *Id.*
[55] Silvio De Flora, Carlo Bennicelli, Anna Camoirano, and Patrizia Zanacchi, Genotoxicity of nitrosated ranitidine, CARCINOGENESIS, Vol. 4, No. 3, pp. 255-260 (1983).
[56] Annalisa Maura, Albiana Pino, Luigi Robbiano, Enrica Cajelli, Renata Finollo, Marco Cavanna and Giovanni Brambilla, DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells, TOXICOLOGY LETTERS, 18, 97-102 (1983).

necessarily identical to those found in the human body, it expressly issued a call for more research into the conditions in which nitroso compounds formed as a result of ranitidine ingestion. On information and belief, GSK and the other Defendants knew or had reason to know of this study.

69. Further evidence of GSK's knowledge that Zantac formed NDMA in the body came from a human study GSK was involved in that was published in 1987.[57] In that study, researchers tracked 15 patients who took ranitidine and examined their gastric juices following their ingestion of Zantac. Critically, instead of using mass spectrometry—the gold standard assay at the time (which remains the case today)—to detect the presence of nitrosamines in the human subjects, GSK used a nitrogen-oxide assay, which essentially was designed not to find nitrosamines. Although the assay allegedly can detect N-nitrosamines, the sensitivity of the assay to detect NDMA is not established within the peer-reviewed literature. Even so, when the study team tested gastric fluid samples containing ranitidine, the nitrogen-oxide assay indicated the presence of N-nitroso compounds (for example, NDMA). Rather than exploring this further, the authors claimed these results were "fals[e]" and restricted all tests to "ranitidine free samples" in an obvious effort to avoid high readings of N-nitroso compounds.[58]

70. Upon information and belief, these results were true, and in fact, were yet another warning sign to GSK scientists that ranitidine did and does generate carcinogenic N-nitroso compounds like NDMA. Scientists at Valisure have demonstrated that when ranitidine is incubated in simulated gastric fluid with nitrite, high levels of NDMA are formed. But rather than exploring

[57] J Meyrick Thomas, JJ Misiewicz, AR Cook, MJ Hill, PLR Smith, CL Walters, JK Forster, LE Martin, and DF Woodings, Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents, 28 GUT. at pp. 726-738 (1987).
[58] *Id.*

this issue further, the 1987 study team simply did not test any study samples that had ranitidine in them.

71. In fact, on information and belief, GSK never used a mass spectrometry assay to test for the presence of nitrosamines in this study, or in any of the studies and trials it did in connection with its ranitidine NDA. The self-evident reason is that using GC/MS (which requires heating of up to 130 degrees Celsius), causes excessive amounts of nitrosamines to be formed. If GSK used a GC/MS assay, which necessarily would have resulted in the formation of large amounts of NDMA, the FDA would never have approved Zantac as being safe.

72. More recently, during the time that Defendants were manufacturing and selling over-the-counter Zantac in the United States, the scientific evidence linking Zantac and NDMA grew stronger. For example, a 2011 scientific study found that, of the eight pharmaceuticals that were observed, "ranitidine showed the strongest potential to form N-nitrosodimethylamine (NDMA)" when present in drinking water during chloramine disinfection.[59] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[60] Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[61]

73. A 2014 scientific article that examined the formation mechanisms of NDMA acknowledged the consensus about the dangers posed by ranitidine, observing that ranitidine and

[59] Ruqiao Shen & Susan A. Andrews, Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection, 45 WATER RESEARCH 944 (Oct. 13, 2010).
[60] *Id.* at 948.
[61] Julien Le Roux, et al., Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation, 45 WATER RESEARCH 3164 (Mar. 26, 2011).

two other pharmaceuticals had "recently caused much concern because they are potent NDMA precursors."[62]

74. Notably, a peer-reviewed study published in the scientific journal *Carcinogenesis* in 2016 "confirmed the production of N-nitrosodimethylamine (NDMA), a potent carcinogen, by nitrosation of ranitidine under stomach-relevant pH conditions *in vitro*" and also showed that, during the 24 hours following ranitidine intake, the quantity of NDMA in urine excreted by the patient "increased 400-folds from 100 to 47 600 ng."[63] "The study showed that healthy individuals, both male and female, that took Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 40,000 nanograms) in the proceeding 24 hours."[64] The article noted that these levels of NDMA "equaled or exceeded those observed previously in patients with schistosomiasis, a disease wherein N-nitrosamines are implicated as the etiological agents for bladder cancer."[65] The article also cautioned that these "estimates are conservative"—the "actual systemic exposure to NDMA is likely much higher than that eliminated in urine" since NDMA has "a high metabolic conversion rate" (i.e. >99%) and therefore only about 0.05% of NDMA in the body is excreted in urine.[66] The authors also noted that "alternative medications,

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[62] Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination*: ENVIRONMENTAL SCIENCE & TECHNOLOGY 8653 (June 26, 2014).

[63] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of Nnitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016). William Mitch is a professor of Civil and Environmental Engineering at Stanford University. *William Mitch,* Stanford University, https://cee.stanford.edu/people/william-mitch (last visited Sept. 13, 2019). Teng Zeng is an Associate Professor of Civil and Environmental Engineering at Syracuse University. *Teng Zeng*, Syracuse University College of Engineering & Computer Science, http://eng-cs.syr.edu/ourdepartments/civil-and-environmental-engineering/people/faculty/?peopleid=3322 (last visited September 13, 2019).

[64] Citizen Petition at 11.

[65] Zeng & Mitch, *supra* footnote 63, at 625.

[66] *Id.* at 632.

such as proto pump inhibitors (PPIs), would less likely promote *in vivo* nitrosation because of the lack of amines in their structure."[67]

75. A 2018 scientific review "summarize[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)"[68] again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."[69]

76. Moreover, according to the Petition, "an epidemiological study has implicated ranitidine's drug class as being correlated to cancer."[70]

77. Despite the undeniable scientific evidence linking ranitidine to the production of high levels of NDMA, Defendants did not disclose this link to consumers on Zantac's label or through any other means.

78. Defendants have had notice of serious adverse health outcomes regarding cancer and other injuries associated with their ranitidine products, including Zantac through case reports, clinical studies and post-market surveillance.

79. As such, these numerous reports of cancer, put Defendants on notice as to the excessive risks of injuries related to the use of ranitidine products, including Zantac.

80. Moreover, there are reasonable alternative treatments available to treat the conditions indicated by Zantac, such as another histamine blocker or a proton-pump inhibitor (PPI). Indeed, as the Petition notes, there were numerous alternative medications that Valisure tested where NDMA was not detected.[71]

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[67] Zeng & Mitch, *supra* footnote 63, at 632–33.
[68] Massimiliano Sgroi, et al., *N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal*, 191 CHEMOSPHERE 685 (Oct. 15, 2017).
[69] *Id.* at 698.
[70] Citizen Petition at 4.
[71] *Id.* at 15-16.

81. Defendants knew or should have known that Zantac exposed users to unsafe levels of the carcinogen NDMA based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

82. Despite their knowledge that exposure to unsafe levels of NDMA could result in cancer, Defendants took no action to inform Plaintiff, Plaintiff's physicians and/or the FDA of this known risk. Instead, Defendants continued to represent that their ranitidine products, including Zantac, had been tested and were found to be safe and effective for their indicated use in treating gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions. Defendants promoted and marketed ranitidine products, including Zantac, as safe and effective for individuals such as Plaintiff throughout the United States, including Florida.

83. Defendants negligently and/or recklessly failed to disclose their knowledge that their ranitidine products, including Zantac, contained unsafe levels of NDMA that could cause cancer, from Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

84. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with ranitidine products, including Zantac, including, but not necessarily limited to, long-term usage and the cumulative effects of long-term usage.

85. In omitting, and inadequately providing critical safety information regarding the use of ranitidine products, including Zantac, in order to induce their purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff.

86. Despite notice and knowledge that ranitidine products, including Zantac, contained unsafe levels of NDMA which can cause cancer and other severe health problems, Defendants continued to market and sell ranitidine products, including Zantac, without warning consumers, healthcare providers, and /or the FDA of these significant risks.

87. Consumers, including Plaintiff, and Plaintiff's physicians relied on the Defendants' false representations and were misled as to Zantac's safety.

88. Had Plaintiff known of the risks of cancer and other injuries associated with Zantac, Plaintiff would not have used the drug.

89. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to Plaintiff's ingestion of Zantac, which caused Plaintiff to suffer from cancer and any and all sequelae.

90. Defendants misrepresented and failed to disclose risks of cancer and other injuries associated with Zantac with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Zantac or ranitidine for the treatment of gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare.

91. As a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.

92. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Zantac, which has caused Plaintiff to suffer from cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

TOLLING OF THE STATUTE OF LIMITATIONS

A. Discovery Rule Tolling

93. As a result of the acts and omissions of Defendants, Plaintiff could not have discovered, through the exercise of reasonable due diligence, that exposure to Zantac was associated with increased exposure to NDMA and risk of cancer. Thus, the applicable limitations periods did not begin to accrue until Plaintiff discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions.

B. Fraudulent Concealment Tolling

94. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the increased exposure to NDMA and risk of cancer associated with Zantac throughout the time period relevant to this action.

95. Defendants are under a continuing duty to disclose the true character, quality, and nature of Zantac to Plaintiff. To date, Defendants have nevertheless failed to inform patients and doctors about the increased exposure to NDMA and risk of cancer associated with Zantac, as discussed above.

96. Plaintiff reasonably relied upon Defendants' knowing, affirmative, or active concealment when Plaintiff continued to use Zantac.

97. Because Defendants actively concealed, and continue to actively conceal the increased exposure to NDMA and risk of cancer associated with Zantac, any applicable statutes of limitation have been tolled.

C. Estoppel

98. Defendants were, and are, under a continuous duty to disclose to Plaintiff the increased exposure to NDMA and risk of cancer associated with Zantac. Instead, they actively concealed the true character, quality, and nature of Zantac and knowingly made misrepresentations and/or omissions the increased exposure to NDMA and risk of cancer associated with Zantac.

99. Plaintiff reasonably relied upon Defendants' knowing and affirmative misrepresentations and active concealment of material facts. Therefore, Defendants are estopped from relying on any defense based on statutes of limitations in this action.

COUNT I

[Strict Liability – Design Defect]

100. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

101. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

102. Florida common law requires manufacturers to design reasonably safe products. Defendants have a duty to use reasonable care to design a product that is reasonably safe for its intended use to prevent defects that constitute a substantial risk of foreseeable injury to persons using its products. Moreover, manufacturers stand in a superior position over consumers with

regard to knowledge of, or the ability to discover and prevent, defects. As a result of numerous studies described in detail above, Defendants were aware of the inherent risks of Zantac.

103. Zantac is defective in design and/or formulation due to its inherent risks of producing the carcinogen NDMA, thereby rendering the drug unreasonably dangerous. More specifically, Zantac is defective because the drug is made up of an inherently unstable ranitidine molecule that contains both a nitrate and a dimethylamine ("DMA") group that combine to form a known carcinogen (NDMA), which can lead to the development of cancer.

104. This defect caused serious injury, including cancer, to Plaintiff who used Zantac in its intended and foreseeable manner from the 1980's through 2019.

105. Defendants had a duty to use due care in designing Zantac and to disclose defects that they knew or should have known existed. In other words, Defendants had a duty to design Zantac to prevent it from reacting with itself to produce the carcinogen NDMA. Florida law required Defendants to design Zantac differently. At no time was there a federal law that prohibited Defendants from submitting to FDA a different non-defective design for Zantac.

106. This defect in design and/or formulation existed at the time the drug left Defendants' possession and at the time it was sold to Plaintiff.

107. Zantac was expected to and did reach Plaintiff without a substantial change in condition in which it was sold.

108. At the time Zantac left Defendants' possession, an average consumer could not reasonably anticipate the dangerous nature of Zantac (i.e., the fact that it combines with itself to form NDMA, a potent carcinogen) nor fully appreciate the attendant risk of injury associated with it use, including the risk of developing cancer.

109. Zantac was prescribed to or otherwise used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

110. As a direct and proximate result of Plaintiff's ingestion of Zantac, Plaintiff developed cancer.

COUNT II

[Strict Liability – Failure to Warn]

111. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

112. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

113. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Zantac to Plaintiff and/or Plaintiff's prescribing physicians. Additionally, Defendants expected the Zantac that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Zantac did in fact reach – prescribing physicians and consumers, including Plaintiff and the prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

114. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and used by Plaintiff. The defective condition of Zantac was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing cancer as a result of its use. Defendants were aware that Zantac produces NDMA and failed to include proper warnings.

115. This defect caused serious injury, including cancer, to Plaintiff who used Zantac as intended and in a foreseeable manner.

116. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

117. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

118. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Zantac, namely its potential to cause cancer as a result of the production of NDMA.

119. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Zantac caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing cancer from Zantac use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

120. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

121. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

122. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

123. Had Defendants properly disclosed the risks associated with Zantac, including cancer, Plaintiff would not have used Zantac.

124. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

COUNT III

[Negligence]

125. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

126. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

127. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Zantac.

128. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

129. This defect caused serious injury, including cancer, to Plaintiff who used Zantac in its intended and foreseeable manner.

130. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Zantac;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Zantac's dangerous and defective characteristics, including that it can produce NDMA;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the ranitidine and/or Zantac;

d) In promoting Zantac in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause cancer;

e) In representing that Zantac was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of Zantac;

g) In failing to perform appropriate post-market surveillance of Zantac;

h) In failing to adequately and properly test Zantac before and after placing it on the market;

i) In failing to conduct sufficient testing on Zantac which, if properly performed, would have shown that Zantac could react with itself to produce the carcinogen NDMA;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Zantac carried a risk of developing cancer;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of cancer associated with the use of Zantac; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely cancer, from Zantac ingestion as described herein.

131. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care. Defendants were aware that multiple studies were conducted showing that ranitidine produces NDMA, a potent carcinogen.

132. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, cancer. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

COUNT IV

[Breach of Express Warranty]

133. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

134. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

135. Through Defendants' public statements, descriptions, and promises relating to Zantac, Defendants expressly warranted that the product was safe and effective for its intended use and was designed to prevent and relieve heartburn associated with acid indigestion and sour stomach associated with acid indigestion brought on by eating or drinking certain foods and beverages.

136. These warranties came in one or more of the following forms: (a) publicly made written and verbal assurances of safety; (b) press releases, media dissemination, or uniform promotional information intended to create demand for Zantac, but which contained misrepresentations and failed to warn of the risks of using the product; (c) verbal assurances made by Defendants' marketing personnel about the safety of Zantac, which also downplayed the risks associated with the product; and (iv) false, misleading, and inadequate written information and packaging supplied by Defendants.

137. When Defendants made these express warranties, they knew the intended purposes of Zantac and warranted the drug to be in all respects safe and proper for such purposes.

138. Defendants drafted the documents and/or made statements upon which these warranty claims were based and, in doing so, defined the terms of those warranties.

139. Zantac does not conform to Defendants' promises, descriptions, or affirmations, and is not adequately packaged, labeled, promoted, and/or fit for the ordinary purposes for which it was intended.

140. All of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiff's belief that these materials shall be produced by Defendants and made part of the record once discovery is completed.

141. As a direct and proximate result of Defendants' breach of these warranties, Plaintiff suffered serious injuries and/or side effects, including cancer.

142. As a direct and proximate result of Defendants' breach of the implied warranties, Plaintiff will require and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

143. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

COUNT V

[Breach of Implied Warranty]

144. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

145. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

146. At all times material to this action, Defendants were merchants Zantac.

147. Plaintiff was a foreseeable user of Zantac.

148. At the time Defendants marketed, sold, and distributed Zantac, Defendants knew of the intended use of the drug, impliedly warranted the drug to be fit for a particular purpose, and warranted that the drug was of merchantable quality and effective for such use.

149. Defendants knew or had reason to know that Plaintiff would rely on Defendants' judgment and skill in providing Zantac for its intended use.

150. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Zantac was of merchantable quality, safe, and effective for its intended use.

151. Contrary to Defendants' implied warranties, Zantac is neither of merchantable quality, nor safe or effective for its intended use, because the device is unreasonably dangerous, defective, unfit, and ineffective for the ordinary purposes for which it is used. Specifically, Zantac is unreasonably dangerous because it can react with itself and produce NDMA, a potent carcinogen.

152. Zantac was sold without adequate instructions or warnings regarding the foreseeable risk of harm posed by the drug.

153. In violation of Fla. Stat. Ann. §§ 672.314, et seq., Defendants breached their implied warranty to Plaintiff in that Zantac was not adequately tested and was not of merchantable quality, safe, or fit for its foreseeable and reasonably intended use.

154. Plaintiff could not have discovered that Defendants breached their warranty or the danger in using Zantac.

155. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff suffered serious injuries and/or side effects, including cancer.

COUNT VI

[Negligent Misrepresentation]

156. Plaintiff re-alleges paragraphs 1 through 99 of the Complaint as if set out here in full.

157. Each Defendant engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac, on the respective dates set forth above, including to Plaintiff.

158. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Zantac and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Zantac.

159. Defendants made reckless or negligent misrepresentations and negligently and/or recklessly concealed adverse information when Defendants knew, or should have known, that Zantac had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

a. the defective, improper, negligent, fraudulent, and dangerous design of Zantac;

b. that ranitidine had not been adequately tested prior to product launch;

c. the connection between ranitidine/Zantac and NDMA formation;

d. that ranitidine and Zantac can produce NDMA at harmful levels;

e. that harmful levels of NDMA causes cancer;

f. the inadequacy of the labeling for Zantac; and

g. the dangerous effects of Zantac.

160. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

161. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

162. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of Zantac by Plaintiff as well as the general public.

163. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware that Zantac produces NDMA, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken Zantac.

164. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Zantac and relied on the absence of information regarding the dangers of Zantac which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

165. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Zantac in a timely manner.

166. Defendants made the representations and actively concealed information about the defects and dangers of Zantac with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

167. Defendant GSK's active concealment is particularly evident by the 1987 study, as discussed above, in which GSK participated in a human study involving ranitidine and deliberately manipulated the study to prevent those involved from discovering that ranitidine breaks down in NDMA.

168. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff suffered serious injuries, including cancer.

169. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

170. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Zantac;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For expenses and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: 5/20/2020

Respectfully Submitted,
/s/*Fletcher V. Trammell*
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