UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION	**MDL NO. 2924** **20-MD-2924**
HILDA A. PICKNEY and JOSEPH PICKNEY Plaintiffs, vs. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNAITONAL GMBH; BOEHRINGER INGELHEIM USA CORPORATION, GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE, PLC; PFIZER INC.; SANOFI US SERVICES INC.; SANOFI S.A.; SANOFI-AVENTIS US LLC; CHATTEM, INC.; and DOE DEFENDANTS 1-100, Defendants.	**JUDGE ROBIN L. ROSENBERG** **MAGISTRATE JUDGE BRUCE E. REINHART** COMPLAINT [& JURY DEMAND] **CIVIL ACTION NO. _____**

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THIS DOCUMENT RELATES TO:
Hilda A. Pickney v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.

Plaintiffs, by and through undersigned counsel, hereby bring this Complaint for damages against Defendants: Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim USA Corporation, GlaxoSmithKline, LLC; GlaxoSmithKline, PLC; Pfizer Inc.; Sanofi US Services Inc.; Sanofi S.A.; Sanofi-Aventis US LLC; Chattem Inc.; and Doe Defendants 1-100, and allege the following:

INTRODUCTION

1. When laboratory researchers want to study tumors in experimental animals, the toxin of choice to induce tumors in experimental animals is often N-Nitrosodimethylamine (NDMA).

Unfortunately, the manufacturers of Zantac and ranitidine[1] have been poisoning American consumers with extremely high levels of NDMA for over 35 years. A single dose of Zantac, chemically known as ranitidine, has been shown to break down inside the body into over three million nanograms of NDMA. This is over 30,000 times higher than the threshold level of 96 nanograms per day. The FDA has also stated that early tests conducted by the FDA have found "unacceptable levels" of NDMA in samples of ranitidine. NDMA is a probable human carcinogen.

2. Plaintiff Hilda Pickney took Zantac for over 3 years, and as a result, was diagnosed with breast cancer on May 20, 2019. Plaintiff's cancer was caused by NDMA exposure due to plaintiff's daily ingestion of Zantac.

3. 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, marketing, advertising, promoting, labeling, distribution and/or sale of the drug Zantac. Plaintiff alleges that Zantac is defective, dangerous to human health, and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

PARTIES

4. Plaintiff Hilda Pickney is a natural person and at all relevant times a resident and citizen of Saint Landry County, Louisiana. Plaintiff brings this action for personal injuries sustained by the use of Zantac.

[1] All subsequent references to "Zantac" in this complaint refer also to ranitidine, both as an independent active ingredient, as well as a finished medication.

5. Plaintiff Joseph Pickney is a natural person and at all relevant times was and is the legal spouse of Plaintiff Hilda Pickney, and brings this action for loss of consortium claims as further specified below.

I. The Brand Manufacturer Defendants

6. Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer Ingelheim Pharmaceuticals, Inc. is a citizen of Connecticut and Delaware, and not of any other state. Boehringer Ingelheim Pharmaceuticals, Inc. is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer Ingelheim Pharmaceuticals, Inc. owned and controlled the new drug applications ("NDA") for over-the-counter ("OTC") Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period. At all relevant times, Boehringer Ingelheim Pharmaceuticals, Inc. has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

7. Defendant, Boehringer Ingelheim International GmbH, is a German multinational pharmaceutical corporation with its principal place of business located at Binger Strasse 173 55216 Ingelheim am Rhein, Germany. Boehringer Ingelheim International GmbH is the parent company of Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. At all relevant times, Boehringer Ingelheim International GmbH has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

8. Defendant, Boehringer Ingelheim USA Corporation, is a Delaware corporation with its principal place of business located in at 900 Ridgebury Rd., Ridgebury, Connecticut 06877. Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut and is not a citizen of any other state. At all relevant times, Boehringer Ingelheim USA Corporation has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

9. Collectively, Defendants, Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation, shall be referred to as "BI."

10. Defendant, GlaxoSmithKline, LLC, is a Delaware limited liability 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. GSK is a citizen of Delaware and North Carolina. At all relevant times, GSK has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

11. Defendant, GlaxoSmithKline, plc, is a foreign entity and a citizen of the United Kingdom, and is not a citizen of any state in the United States, with its principal place of business located at 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. 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 & Hanburys Ltd., which was a subsidiary of Glaxo Labs Ltd. Allen & Hanburys 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, the FDA granted approval to Glaxo Holdings, Ltd. to sell Zantac in the United States. Glaxo Holdings, Ltd. was later absorbed into Glaxo Wellcome, PLC. And then, in 2000, GlaxoSmithKline, plc and GlaxoSmithKline, LLC were created by the merger of Glaxo Wellcome and SmithKline Beecham. At all relevant times, GlaxoSmithKline, plc has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

12. Collectively, Defendants, GlaxoSmithKline, LLC and GlaxoSmithKline, plc, shall be referred to as "GSK." GSK, and its predecessors, have controlled the prescription Zantac NDAs since 1983.

13. 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. In 1995, NDA 20-520 Zantac OTC 75 mg tablets were approved. In 1998, NDA 20-745 OTC Zantac 75 mg effervescent tablets were approved. Also upon information and belief, in 1998, 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 United States and Glaxo Wellcome retaining control over the Zantac trademark internationally.[2] In 2000, Pfizer acquired Warner-Lambert and maintained control over the Zantac OTC NDA until December 2006. At all relevant times, Pfizer has conducted business and derived

[2] *See Warner-Lambert and Glaxo End A Venture on Ulcer Drug Zantac*, WALL STREET JOURNAL (Aug. 4, 1998), available at https://www.wsj.com/articles/SB902188417685803000.

substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

14. Defendant, Sanofi US Services Inc., 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 has controlled the NDAs for OTC Zantac since January 2017 following an asset swap with BI and manufactured and distributed the drugs in the United States since then. Sanofi voluntarily recalled all brand name OTC Zantac on October 18, 2019. At all relevant times, Sanofi has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

15. Defendant, Sanofi S.A., is a French multinational pharmaceutical company headquartered in Paris, France, with its principal place of business located at 54, Rue La Boetie, in the 8th arrondissement. Defendant, Sanofi S.A., changed its name to Sanofi in May 2011. As of 2013, Sanofi S.A. was the world's fifth largest pharmaceutical company by prescription sales. At all relevant times, Sanofi S.A. has conducted business and derived substantial revenue from its design, manufacture, marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

16. Defendant, Sanofi-Aventis US LLC, was and is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey and is not a citizen of any

other state. Sanofi-Aventis US LLC is a wholly owned subsidiary of Sanofi S.A. At all relevant times, Sanofi-Aventis U.S. LLC has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within each of the States and Territories of the United States.

17. Collectively, Defendants, Sanofi US Services Inc., Sanofi S.A., and Sanofi-Aventis U.S. LLC, shall be referred to as "Sanofi."

18. Defendant, Chattem, Inc., 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 recent voluntary recall. At all relevant times, Chattem has conducted business and derived substantial revenue from its marketing, advertising, promotion, labeling, packaging, handling, distribution, storage, and sale of Zantac within each of the States and Territories of the United States.

19. Defendants, BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as the "Brand Manufacturer Defendants."

II. The Doe Defendants

20. Doe Defendants 1-100 are active pharmaceutical ingredient (API) manufacturers and distributors, the identity of which cannot be confirmed at this time.

21. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of DOES 1 through 100, inclusive, are unknown to Plaintiff at this time, who therefore sues Defendants by such fictitious names. Plaintiff is informed and believes, and thereon alleges, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as hereinafter alleged; and that each DOE

Defendant is liable to Plaintiff for the acts and omissions alleged herein below, and the resulting injuries to Plaintiff, and damages sustained by the Plaintiff. Plaintiff will amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

22. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE Defendants, and each of them, and at all said times, each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

23. Active Pharmaceutical Ingredient Manufacturers ("API Manufacturers") sell to finished dose manufacturers, who then sell the Ranitidine-Containing Products to distributors, who then distribute and sell the products to retailers, including, but not limited to, pharmacies, drug stores, and grocery stores, etc., who dispense them to patients, such as Plaintiffs.

24. Upon information and belief, both the Brand Name and Generic Defendants obtained API from Doe Defendants, and Doe Defendants were negligent in their manufacture of the API, which was then processed into finished dose Zantac and ranitidine, which was subsequently ingested by Decedent.

25. Distributors purchase bulk Ranitidine-Containing Products from the Brand Manufacturer Defendants and Generic Manufacturer Defendants and then sell to retailers, such as pharmacies. Based upon public information, Plaintiff believes the Zantac ingested by Decedent was distributed by Cardinal Health, Inc., McKesson Corporation, and/or Amerisource Bergen Corporation but has declined to name them at this time until discovery has provided additional information.

JURISDICTION AND VENUE

1. 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.

2. Venue is proper in the Western District of Louisiana Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business in this District and are subject to personal jurisdiction in this District. Furthermore, Defendants sold, marketed and/or distributed Zantac within Georgia and this District. However, this Complaint is being filed into the MDL pursuant to this Court's Direct Filing Order and is without prejudice to Plaintiff's *Lexecon* rights, which Plaintiff hereby expressly reserves.

FACTUAL ALLEGATIONS

I. A Brief History of Zantac and Ranitidine

1. Zantac was developed by Glaxo – now known as GlaxoSmithKline ("GSK"), post-merger – 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.

2. Due in large part to GSK's marketing strategy, Zantac was a wildly successful drug. Zantac was the world's best-selling drug in 1988 and in the fiscal year that ended in June 1989, Zantac accounted for over half of Glaxo's sales of $3.98 billion. Even as late as 2016, Zantac was the 50th most prescribed drug in the United States with over 15 million prescriptions. The marketing strategy that led to Zantac's success for over 30 years emphasized the purported safety of the drug. Zantac has been marketed as a safe and effective treatment for infants, children, and adults.

3. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year.
4. On September 13, 2019, in response to a citizen's petition filed by Valisure, Inc., U.S. and European regulators stated that they are reviewing the safety of ranitidine.
5. 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.
6. On September 28, 2019, CVS Health Corp. announced that it would stop selling Zantac and its own generic ranitidine products out of concern that it might contain a carcinogen. Walmart, Inc., Walgreens, and Rite Aid Corp have announced removed Zantac and ranitidine products from their shelves.
7. On October 2, 2019, the FDA stated that it was requiring all manufacturers of Zantac and ranitidine products to conduct testing for NDMA and that preliminary testing results indicated unacceptable levels of NDMA.
8. On October 18, 2019, Sanofi recalled all of its Zantac OTC in the United States, which included Zantac 150, Zantac 150 Cool Mint, and Zantac 75.
9. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to heat levels that would occur during transport and storage.
10. Emery's Citizen Petition outlined its substantial concern that Ranitidine is a time- and temperature-sensitive pharmaceutical product that develops a known carcinogen, NDMA, when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship Ranitidine-Containing Products in temperature-controlled vehicles.

11. In response,[3] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[4] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[5] The FDA found that the recall of all Ranitidine-Containing Products and public warning of the recall was necessary because the "product being recalled presents a serious health risk."[6] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[7]

12. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine products stored at room temperature can increase with time to unacceptable levels. Other testing conducted by FDA revealed a correlation between NDMA levels and expiration date. The FDA's testing eroded the agency's confidence that any ranitidine product could remain stable through its labeled expiration date. Consequently, the FDA was compelled to order the products off the market. The FDA's decision to ban the drug rendered moot Emery's request for temperature-controlled sales conditions.

13. The FDA therefore issued a public statement requesting the immediate removal of all Ranitidine-Containing Products from the market due to the risk to public health.[8] "The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable

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3 Letter of Janet Woodcock, Docket No. FDA-2020-P-0042 (April 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

4 *Id., citing* 21 CFR 7.40(a).

5 *Id.*

6 *Id.*

7 *Id.,* fn. 43.

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

levels of this impurity." Based upon its own testing and evaluation, the FDA concluded that "NDMA levels increase in ranitidine even under normal storage conditions and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers."

14. The FDA's reaction to the NDMA crisis involving ranitidine has come under attack. Over 43 different countries and jurisdictions took action to restrict or ban ranitidine-containing products before the FDA took any action.[9]

15. 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 Changes Being Effected regulation. Had any Defendant attempted to add an NDMA warning to the Zantac label (either for prescription or OTC), the FDA would have not rejected it.

II. The Dangers of NDMA

16. 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. NDMA is longer produced or commercially used in the United States, except for the purpose of inducing tumors in laboratory animals.

17. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable carcinogen. The World Health Organization ("WHO") has stated that scientific testing indicates that NDMA

[9] Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes haphazard—and the agency doesn't want more authority to protect consumers*, Bloomberg Businessweek (Dec. 3, 2019), *available at* https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

18. Beginning in July 2018, the FDA has recalled several generic blood pressure medications, such as: valsartan, losartan, and irbesartan, because the medications contained nitrosamine impurities that exceeded the 96 nanogram acceptable daily threshold set by the FDA. The highest levels detected by the FDA in valsartan pills were over 20,000 nanograms per pill. In the case of Valsartan, NDMA was deposited into the pill due to a manufacturing defect, and therefore, NDMA was present in only some of the valsartan containing products. For Zantac, NDMA is a byproduct of the ranitidine molecule itself, and the levels observed in recent testing show NDMA levels in excess of 3,000,000 nanograms. In addition, NDMA has been a byproduct of the ranitidine molecule since it was first marketed in the U.S. in 1983. Therefore, Zantac consumers will have been exposed to millions of nanograms of NDMA from 1983 until Zantac was recently pulled off the pharmacy shelves.

19. In animal studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the stomach, liver, kidney, bladder, pancreas and other organs.

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

21. Numerous *in vitro* studies confirm that NDMA is a mutagen that causes mutations in human and animal cells.

22. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous epidemiological studies exploring the effects of NDMA dietary exposure to various cancers. The exposure levels considered in these studies are a very small fraction – as little as 1 millionth

– of the exposure levels from a single Zantac pill, i.e., 0.191 ng/day (dietary) versus 304,500 ng/day (Zantac).

23. 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.[10]

24. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[11]

25. 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.[12]

III. How Ranitidine Transforms into NDMA Within the Body

26. 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 a dimethylamine ('DMA') group which are well known to combine to form NDMA. Thus, ranitidine produces NDMA by "react[ing] with itself", which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.

27. 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

[10] 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).
[11] 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).
[12] 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).

contamination of the American water supply.[13] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[14]

28. 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.

29. 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 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 nanograms.[15] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

30. Valisure's testing shows over 2 million nanograms of NDMA in a 150 mg Zantac pill. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at ***28,000 times*** the permissible 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.

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[13] 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).

[14] Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).

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

31. Valisure also tested ranitidine pills 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.

32. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[16]

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

34. 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.

35. 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 present in the warning labels of antacids like Prevacid and was specifically studied with ranitidine in the original approval of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

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16 *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.

36. 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.

37. 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 dimethylamine ("DMA") – which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

38. 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.

39. 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]."[17]

[17] 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).

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

41. 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.

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

43. 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.[18]

44. 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.[19] 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,

[18] Zeng et al, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 625-634 (2016).

[19] 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, 250-254 (2004).

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.

45. 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 nitrite resulted in a significant DNA fragmentation.[20]

46. 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 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[.]"

IV. Defendants Knew of the NDMA Defect but Failed to Warn or Test

47. 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.

48. 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.

[20] Brambilla et al, *Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance*, Nicolini C. (eds) Chemical Carcinogenesis. NATO Advanced Study Institutes Series (Series A: Life Sciences), Vol 52. Springer, Boston, MA (1982).

49. 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.

50. 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.

51. "The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product." 21 C.F.R. § 314.81(b)(2)(v).

52. 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.

53. 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.

54. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[21] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believe this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product.

55. 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.[22] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk.

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

V. Plaintiff-Specific Allegations

57. Plaintiff began using Zantac in approximately February 2015 and used it through April 2019.

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[21] 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).

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

58. In May of 2019, Plaintiff was diagnosed with breast cancer.

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

60. Plaintiff's breast cancer was caused by ingestion of Zantac.

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

Count I: Strict Liability – Design Defect

62. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

63. Defendants designed, manufactured, marketed, promoted, sold, supplied and/or distributed Zantac.

64. Louisiana 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.

65. 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.

66. 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. Louisiana 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.

67. 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.

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

69. At the time Zantac left Defendants' possession, an average consumer could not reasonably anticipate the dangerous nature of Zantac nor fully appreciate the attendant risk of injury associated with it use, including the risk of developing cancer.

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

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

72. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count II: Strict Liability – Failure to Warn

73. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

74. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Zantac, and through that conduct have knowingly and intentionally placed Zantac into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff.

75. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Zantac to Plaintiff and to her 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 her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

76. 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.

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

78. 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.

79. 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.

80. 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.

81. 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.

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

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

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

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

86. 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.

87. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count III: Strict Liability – Manufacturing Defect

88. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

89. At all times herein mentioned, Defendants designed, distributed, manufactured, sold, tested, and marketed the drugs ingested by Plaintiff to patients and physicians.

90. At all relevant times, the Zantac ingested by Plaintiff was expected to and did reach Plaintiff without a substantial change in its condition as manufactured, distributed, shipped, stored, and sold by Defendants.

91. At all relevant times, the Zantac ingested by Plaintiff contained manufacturing defects, in that it differed from the approved design and specifications of drug because it contained dangerous amounts of NDMA, a new active ingredient.

92. At all relevant times, the medications ingested by Plaintiffs further contained manufacturing defects, in that they were not bioequivalents to the FDA-approved design for Zantac, thereby rendering these products unreasonably dangerous to patients such as Plaintiff.

93. Defendants were required to manufacture a drug that conformed to FDA-approved specifications, such that the drugs manufactured were equal substitutes to the approved design for ZAntac, which did not contain nitrosamines. These drugs were required to be biologically the "same as an already marketed brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[23]

94. Defendants failed to meet the requirements mentioned in the paragraph above by utilizing flawed and unlawful manufacturing, storage, and shipping processes that were unvalidated and unsafe and by violating Current Good Manufacturing Practices.

95. Instead, Defendants manufactured a different drug, containing additional active and harmful ingredients.

96. At all relevant times, the medications ingested by Plaintiff were used in a manner that was foreseeable and intended by Defendants.

97. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

[23] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

Count IV: Negligence

98. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

99. 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.

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

101. 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;
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.

102. 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.

103. 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, kidney 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.

104. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count V: Breach of Express Warranty

105. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

106. 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.

107. 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 (d) false, misleading, and inadequate written information and packaging supplied by Defendants.

108. 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.

109. 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.

110. 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.

111. 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.

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

113. 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.

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

115. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count VI: Breach of Implied Warranty

116. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

118. Plaintiff was a foreseeable user of Zantac.

119. 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.

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

121. 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.

122. 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.

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

124. 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.

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

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

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

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

129. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count VII: Negligent Misrepresentation

130. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

131. 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.

132. 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 and Zantac and NDMA formation;
d. that ranitidine and Zantac can produce NDMA at harmful levels;
e. that harmful levels of NDMA is carcinogenic;
f. the inadequacy of the labeling for Zantac; and

g. the dangerous effects of Zantac.

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

134. 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.

135. 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.

136. 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 of said facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken Zantac.

137. 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.

138. 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.

139. 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.

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

141. 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.

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

143. As a direct and proximate result of these manufacturing defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Count IX: Loss of Consortium

144. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

145. At all relevant times, Plaintiff Joseph Pickney, was the lawful spouse of Plaintiff Hilda Pickney, and as a direct and proximate result of negligence, actions, representations, and omissions as set forth above, Plaintiff, Joseph Pickney, has suffered the loss of his spouse's support and services, companionship, protection, consortium, and the care and comfort of her society. These losses are either permanent to continuing in nature, and Joseph Pickney will suffer these losses 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 punitive and exemplary damages according to proof;
H. For expenses and costs of this action; and
I. For such further relief as this Court deems necessary, just, and proper.

Dated: 5/20/2020

Respectfully Submitted,
/s/*Marlene J. Goldenberg*
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