UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION	**MDL No: 2924** **CASE No: 20-MD-2924**
	JUDGE ROBIN L. ROSENBERG
PAMILA WILBANKS,	**MAGISTRATE JUDGE BRUCE E. REINHART**
Plaintiff,	COMPLAINT & JURY DEMAND
v.	**CIVIL ACTION NO. _____**

PFIZER, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; SANOFI; CHATTEM, INC.; SANOFI US SERVICES INC.; SANOFI-AVENTIS U.S. LLC; GLAXOSMITHKLINE, PLC; and GLAXOSMITHKLINE, LLC,

Defendants.

THIS DOCUMENT RELATES TO: PAMILA WILBANKS v. PFIZER, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; SANOFI; CHATTEM, INC.; SANOFI US SERVICES INC.; SANOFI-AVENTIS U.S. LLC; GLAXOSMITHKLINE, PLC; and GLAXOSMITHKLINE, LLC.

COMPLAINT

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"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), and alleges the following based on personal knowledge, the investigation of counsel, and information and belief:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Sanofi Defendants' and Boehringer's 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.

PARTIES

2. Plaintiff Pamila Wilbanks is a natural person and at all relevant times a resident and citizen of Vermillion County, Indiana. Plaintiff brings this action for personal injuries sustained by the use of Zantac. Plaintiff regularly ingested Zantac from the 1980's to early 2020. As a direct and proximate result of ingesting Zantac, Plaintiff developed uterine cancer and underwent complete hysterectomy surgery in 2018.

3. Defendant GlaxoSmithKline, PLC is a United Kingdom public limited company. It is the successor-in-interest to companies that initially developed ranitidine.

4. Defendant GlaxoSmithKline, LLC is a Delaware limited liability company with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania 19112 and 5 Moore Drive, Research Triangle, North Carolina 27709. Defendant GlaxoSmithKline, LLC is a wholly-owned subsidiary of Defendant GlaxoSmithKline, PLC.

5. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Defendant Pfizer, Inc. controlled the rights to Zantac in the United States until 2006. During that time period, it manufactured and distributed the drug in the United States.

6. 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.

7. 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.

8. 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.

9. 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.

10. Upon information and belief, the Sanofi Defendants are or were the manufacturers and distributors of Zantac products. At all times relevant hereto, 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.

11. Upon information and belief, at all relevant times, the Sanofi Defendants were present and doing business in the State of Indiana, and transacted, solicited, and conducted business in the State of Indiana 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 Indiana.

12. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“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. Boehringer owned the U.S. rights to Zantac from about October 2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

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

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

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action and venue is proper pursuant to Pretrial Order 11.

FACTUAL ALLEGATIONS

A. A Brief History of Zantac

16. Zantac was developed by Glaxo - now GlaxoSmithKline - and approved for prescription use by the FDA in 1983.[1] 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]

17. Due in large part to Glaxo's marketing strategy, Zantac was a tremendously successful drug, reaching $1 billion in total sales in December 1986.[3] As one 1996 article put it, 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."[4] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[5] Indeed, Zantac has been marketed as a safe and effective treatment for infants, children, and adults.

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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] *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.

[3] *See* Wright, *supra* footnote 1, at 27.

[4] *See id.* at 25.

[5] *See id.* at 27.

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

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

20. Zantac became available without a prescription in 1996,[6] and generic versions of the drug (ranitidine) became available the following year.[7] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[8] 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[9]-a 3.1 % increase from the previous year.[10]

21. Over the past 20 years, the rights to Zantac in the U.S. have changed hands several times.

22. The Sanofi Defendants 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

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[6] *Id.* at 28.

[7] David Ranii, *Generic Zantac on market,* NEWS AND OBSERVER (Aug. 5, 1997).

[8] *GlaxoSmithKline - Product Portfolio,* PHARMACEUTICALS COMPANY ANALYSIS (Jan.21,2003).

[9] *9 Sales growth of leading brands of antacid tablets in the United States in 2018 (change to prior sales year),* STATISTA (last visited Sept. 13, 2019), https://www.statista.com/statistics/l94547/us-salesgrowth-of-antacid-tablet-brands-in-2013/.

[10] *Id.*

ix. Zantac (Ranitidine Injection)

x. Zantac (Ranitidine Syrup)

xi. Zantac (Ranitidine Tablets and Capsules)

xii. Zantac Cool Mint

xiii. Zantac Injection

23. As relevant here, Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006,[11] and manufactured and sold the drug in the United States - including in Indiana - from approximately January 2007 to January 2017.[12]

24. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and have since that time been manufacturing and selling the drug in the United States, including in Indiana.[13]

B. The Dangers of N-Nitrosodimenthylamine (NDMA)

25. "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."[14]

26. 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

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[11] *Boehringer Ingelheim Pharmaceuticals, Inc. Announces Agreement to Acquire Zantac® from Johnson & Johnson and the Pfizer Consumer Healthcare Business*, BUSINESS WIRE (Oct. 12, 2006).

[12] *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).

[13] *Id.*

[14] *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.

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. This substance is reasonably anticipated to be a human carcinogen."[15] NDMA is also used to create cancer in rats for cancer research.[16]

27. 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."[17] The World Health Organization (WHO) similarly reported in 2002 that "NDMA has been consistently potently carcinogenic in all experimental species examined."[18] As a result, the WHO has recognized that "NDMA is clearly carcinogenic. There is overwhelming evidence that NDMA is mutagenic and clastogenic."[19] NDMA is no longer produced or commercially used in the United States, except for research.[20] In other words, it is only a poison.

28. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[21] The WHO has stated that scientific testing indicates that

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[15] https://pubchem.ncbi.nlm.nih.gov/compound/N-Nitrosodimethylamine (accessed September 25, 2019).

[16] https://cancerres.aacrjoumals.org/content/canres/51/23_Part_2/6452.full.pdf (accessed September 25, 2019).

[17] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, THE GLOBE AND MAIL (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NOMA), 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").

[18] 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.

[19] 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.

[20] *Technical Fact Sheet*, *supra* footnote 14.

"NDMA consumption is positively associated with either gastric or colorectal cancer" and "suggests that humans may be especially sensitive to the carcinogenicity of NDMA."[22] The FDA also recognizes the danger of such compounds, setting strict daily acceptable intake limits of NDMA in pharmaceuticals of 96 ng.[23]

29. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.[24]

30. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure-valsartan, losartan, and irbesartan - because the medications "contain[ed] nitrosamine impurities that don't meet the [FDA's] safety standards.[25] which again provide that the intake of NDMA in pharmaceuticals should be no more than 96 ng.[26] 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.[27] 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.

31. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying

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[21] *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.

[22] *Id.*

[23] 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.

[24] *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).

[25] *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.

[26] *Id.*

[27] *See Laboratory analysis of valsartan products,* FDA (May 2, 2019), *https://www.fda.gov/*drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products.

the FDA-recommended GC/MS protocols for detecting NDMA - the same protocols used by the FDA to detect NDMA in valsartan[28] - 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.[29]

32. 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."[30] Thus, ranitidine produces NDMA by "react[ing] with itself,"[31] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[32]

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.

33. Valisure, LLC is an online pharmacy currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration Pharmacy: FV7431137, Laboratory: RV0484814) and the FDA (FEI #: 3012063246). 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.

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[28] *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.

[29] *See* Citizen Petition, attached as "Exhibit A," at 5; *Combined N-Nitrosodimethylamine*, *supra* footnote 28

[30] Ex. A at 19.

[31] *1d.* at 2.

[32] *1d.* at 1,6.

34. Valisure confirmed the link between ranitidine and NDMA formation during its routine analysis of drug products in its pharmacy.

35. Valisure submitted its Citizen's Petition (the "Petition") to the FDA on September 13, 2019. A copy of the Petition is attached as Exhibit "A".

36. On September 13, 2019, the Food and Drug Administration ("FDA") issued a public statement that some ranitidine medicines, including Zantac, contain an impurity called N-nitrosodimethylamine (NDMA).

37. In response, numerous countries in Europe have withdrawn ranitidine-based drugs from the market. Other drug makers have halted distribution of Zantac in all its markets, including Canada and the United States. Pharmacy chains like Walgreens, Rite-Aid and CVS have also pulled Zantac from their store shelves.

38. As the Petition points out, *in vivo* studies have strongly suggested ranitidine's formation of NDMA and carcinogenicity for decades. For example, a 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, ranitidine administered with nitrite resulted in a "significant DNA fragmentation."[33] Thereafter, in 1983, another study published in the journal *Carcinogenesis* titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite."[34] The authors of this study concluded: "Our experimental findings have shown that simultaneous oral administration in rats of high doses of ranitidine and NaN02 [nitrite]

[33] Brambilla G., Cavanna M., De Flora S. (1982). Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance. In: Nicolini C. (eds) Chemical Carcinogenesis. NATO Advanced Study Institutes Series (Series A: Life Sciences), Vol 52. Springer, Boston, MA https://link.springer.com/chapter/10.1007/978-14684-4334-9_11).

[34] Brambilla, G. et al. (1983). Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite. *Carcinogenesis.* Vol. 4, 10, p. 1281-1285, *available at* https://academic.oup.com/carcin/article-abstract/4/10/1281/2391364.

can produce DNA fragmentation either in liver or in gastric mucosa."[35]

39. 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.[36] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[37] Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[38]

40. A 2014 scientific article that examined the formation mechanisms of NDMA acknowledged the consensus about the dangers posed by ranitidine, observing that ranitidine and two other pharmaceuticals had "recently caused much concern because they are potent NDMA precursors"[39]

41. 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

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[35] Exhibit A at 11.

[36] Ruqiao Shen & Susan A. Andrews, *Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors duringchloramine disinfection,* 45 WATER RESEARCH 944 (Oct. 13, 2010); "Chloramination is the process of adding chloramine to drinkingwater to disinfect it and kill germs. Chloramination is sometimes used as an alternative to chlorination." *Disinfection with Chloramine,* CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 20, 2015), https://www.cdc.gov/healthywater/drinking/public/chloramine disinfection.html.

[37] Shen & Andrews, *supra* footnote 36, at 948.

[38] Julien Le Roux, et al., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 WATER RESEARCH 3164 (Mar. 26, 2011).

[39] Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study,* 48 ENVTL. SCI. & TECHNOLOGY 8653 (June 26, 2014).

to 47 600 ng."[40] "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."[41] 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."[42] 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.[43] The authors also noted that "alternative medications, such as proto pump inhibitors (PPls), would less likely promote *in vivo* nitrosation because of the lack of amines in their structure."[44]

42. A 2018 scientific review "summarize[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)"[45] again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."[46]

43. Moreover, according to the Petition, "an epidemiological study has implicated ranitidine's

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[40] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 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-12 cs.syr.edu/ourdepartments/civil-and-environmental-engineering/people/faculty/?peopleid=3322 (last visited September 13, 2019).

[41] Ex. A at 11,

[42] Zeng & Mitch, *supra* footnote 40, at 625.

[43] *Id. at 632.*

[44] *Id.* at 632-33.

[45] 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).

[46] *Id.* at 698.

drug class as being correlated to cancer."[47]

44. 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.

45. 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.

46. 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, and yet those products remain easily accessible to consumers such as Plaintiff.

47. 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."[48]

48. 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.

49. Despite their knowledge that exposure to unsafe levels of NDMA could result in cancer, Defendants took no action to inform Plaintiff, Plaintiffs physicians and/or the FDA of this known risk. Instead, Defendants continued to represent that their ranitidine products, including Zantac, had been

[47] Ex. A at 4.
[48] *Id.* at 15-16.

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 Indiana.

50. 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 Plaintiffs treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

51. 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.

52. 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.

53. 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.

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

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

56. 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.

57. 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.

58. 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.

59. 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.

COUNT 1
[Strict Liability – Design Defect]

60. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

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

62. Indiana 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.

63. 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.

64. 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. Indiana law required Defendants to design Zantac differently. At no time was there a federal law that prohibited Defendants from submitting to the FDA a different non-defective design for Zantac.

65. 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.

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

67. 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.

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

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

70. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT II
[Strict Liability - Failure to Warn]

71. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

72. 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.

73. 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, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

74. 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.

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

76. 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.

77. 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.

78. 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.

79. 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.

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

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

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

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

84. 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, and all such other and further relief as this Court deems just and proper.

COUNT III
[Negligence]

85. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

86. 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.

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

88. 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 Plaintiffs 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.

89. 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.

90. 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, uterine 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, and all such other and further relief as this Court deems just and proper.

COUNT IV
[Breach of Express Warranty]

91. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

92. 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.

93. 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.

94. 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.

95. 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.

96. 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.

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

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

99. 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.

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for Compensatory and punitive damages, together with interest, costs herein incurred, and all such other and further relief as this Court deems just and proper.

COUNT V
[Breach of Implied Warranty]

101. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

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

103. Plaintiff was a foreseeable user of Zantac.

104. 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.

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

106. 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.

107. 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.

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

109. In violation of Indiana Code 26-1-2-314, 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.

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

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

112. 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.

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, and all such other and further relief as this Court deems just and proper.

COUNT VI
[Negligent Misrepresentation]

114. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

115. Defendants negligently and/or recklessly misrepresented to Plaintiff, 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.

116. 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, and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, 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.

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

118. 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, and the healthcare industry.

119. Defendants made these false representations without the exercise of due care knowing that it

was reasonable and foreseeable that Plaintiff, and the health care industry would rely on them, leading to the use of Zantac by Plaintiff as well as the general public.

120. At all times herein mentioned, Plaintiff was not aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had she been aware of said facts, Plaintiff would not have taken Zantac.

121. 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 Plaintiffs detriment.

122. Defendants had a post-sale duty to warn Plaintiff and the general public about the potential risks and complications associated with Zantac in a timely manner.

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

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

125. 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.

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, and all such other and further relief as this Court deems just and proper.

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 this 9th day of July, 2020.

Respectfully submitted,

KOCH & McAULEY P.C.

/s/ *Eric Allan Koch*
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