IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

GEORGE WHITE and
CAROL WHITE,

Plaintiffs,

v.

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.
Serve: Registered Agent
CT Corporation System
20 South Central Avenue
Clayton MO 63105

SANOFI S.A.
Serve: Registered Agent
CSC-Lawyers Incorporating
Service Company
221 Bolivar
Jefferson City MO 65101

SANOFI-AVENTIS U.S., LLC.
Serve: Registered Agent
CSC-Lawyers Incorporating
Service Company
221 Bolivar
Jefferson City MO 65101

SANOFI US SERVICES, INC.
Serve: Missouri Secretary of State
600 W. Main
Jefferson City MO 65101

CHATTEM, INC.
Serve: Missouri Secretary of State
600 W. Main
Jefferson City MO 65101

Case No. _____

JURY TRIAL DEMANDED

PFIZER, INC.
Serve: Registered Agent
CT Corporation System
120 South Central Avenue
Clayton MO 63105

and

GLAXOSMITHKLINE, LLC,
Serve: Registered Agent
CSC-Lawyers Incorporating
Service Company
221 Bolivar
Jefferson City MO 65101

Defendants.

COMPLAINT

Plaintiffs, George and Carol White, by and through undersigned counsel, hereby bring this Complaint for Damages against Defendants Sanofi S.A., Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Chattem Inc, (hereinafter collectively referred to as "Sanofi" or the "Sanofi Defendants"), Boehringer Ingelheim Pharmaceuticals, Inc., (hereinafter referred to as "Boehringer"), Pfizer, Inc. (hereinafter referred to as "Pfizer"), and GlaxoSmithKline, LLC. (hereinafter referred to as "GSK").

INTRODUCTION

1. N-Nitrosodimethylamine ("NDMA") is a potent carcinogen used to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It is toxic to humans.

2. Zantac (chemically known as ranitidine), the popular antacid medication used by millions of people every day, leads to the production of staggering amounts of NDMA when digested by

the human body. A single dose of Zantac breaks down into over three million ng (nanograms) of NDMA. This is more than 30,000 times higher than the U.S. Food and Drug Administration's ("FDA") allowable daily limit of 96 ng (nanograms).

3. These recent revelations by independent researchers have caused widespread recalls of Zantac both domestically and internationally, and the FDA is actively investigating the issue and has issued a preliminary finding that the levels of NDMA found in Zantac are "unacceptable." Indeed, the current owner and controller of the Zantac new drug applications ("NDAs") has recalled all of the Zantac in the United States.

4. To be clear, this is not a contamination case—the level of NDMA that researchers are seeing in Zantac is not the product of a manufacturing error. Rather, the high level of NDMA in Zantac is a result of the way that ranitidine molecules break down in the human digestive system.

5. Plaintiff George White took Zantac on a regular basis for about 20 years and was diagnosed with stomach and esophageal cancer in October of 2019. His cancer was caused by NDMA exposure directly related to his ingestion of Zantac. This lawsuit seeks damages against the Defendants for causing his cancer.

PARTIES

6. Plaintiff George White is a natural person and at all relevant times a resident and citizen of Perry County, Missouri.

7. Plaintiff Carol White is a natural person and at all relevant times a resident and citizen of Perry County, Missouri. Plaintiff Carol White is the spouse of Plaintiff George White and brings a claim for loss of consortium.

8. 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 based on prescription sales. Sanofi S.A. exercised substantial control over its subsidiaries and over the design, testing, manufacture, packaging and/or labeling of Zantac that caused harm to the Plaintiffs for which recovery is sought.

9. Defendant Sanofi-Aventis US 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 US 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. and conducts substantial business in the United States, specifically in the State of Missouri where it is duly licensed to conduct business. Sanofi-Aventis US LLC may be served by serving its registered agent CSC-Lawyers Incorporating Service Company, 221 Bolivar, Jefferson City, MO 65101.

10. Defendant Sanofi US Services, Inc. was and is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services is a citizen of Delaware and New Jersey and is not a citizen of any other state. Sanofi-Aventis Services is a wholly owned subsidiary of Sanofi S.A. and conducts substantial business in the United States, specifically in the State of Missouri. Sanofi U.S. Services is not in good standing in the state of Missouri having been administratively dissolved for failure to file its annual report. Sanofi US Services may be served by serving the Missouri Secretary of State, 600 W. Main, Jefferson City, Missouri 65101.

11. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business at 1715 West 38th Street, Chattanooga, TN 37409. Defendant Chattem is a citizen of Tennessee

and not a citizen of any other state. Defendant Chattem is a wholly owned subsidiary of Sanofi S.A. and conducts substantial business in the United States, specifically in the State of Missouri. Chattem, Inc. is not in good standing in the state of Missouri having been administratively dissolved for failure to file its annual report. Chattem, Inc. may be served by serving the Missouri Secretary of State, 600 W. Main, Jefferson City, Missouri 65101.

12. Upon information and belief, the Sanofi Defendants, and each of them, are or were the manufacturers and distributors of Zantac products. Sanofi controlled the NDA for OTC Zantac starting in January 2017 through the present. At all times relevant hereto, the Sanofic Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ranitidine products, including Zantac.

13. Upon information and belief, at all relevant time, the Sanofi Defendants were present and doing business in the state of Missouri and transacted, solicited and conducted business in the State of Missouri, deriving substantial revenues 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 Missouri.

14. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer is a citizen of Connecticut and is not a citizen of any other state. Boehringer owned the U.S. rights to OTC Zantac between 2006 and January of 2017 and manufactured and distributed the drug throughout the United States (including the State of Missouri) during that period. Boehringer is duly licensed to transact business in the State of Missouri and lists its registered agent as C T Corporation System, 120 South Central Avenue, Clayton, MO 63105.

15. Defendant GlaxoSmithKline is a Delaware corporation with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania 19112 and Five Moore Drive, Research Triangle, North Carolina 27709. GSK is a citizen of Delaware, Pennsylvania and North Carolina and is not a citizen of any other state. GSK is duly licensed to conduct business in the State of Missouri and may be served by serving its registered agent CSC-Lawyers Incorporating Service Company, 221 Bolivar, Jefferson City, MO 65101. GSK was the original innovator of the Zantac drug and controlled the NDA for prescription Zantac between 1983 and 2009. By controlling the Zantac NDA, it also directly controlled the labeling for all Zantac products through 2009. GSK's negligence and misconduct related to Zantac as an innovator directly led to the failure to warn for other OTC versions of Zantac.

16. 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. Pfizer conducts substantial business in the United States, specifically in the State of Missouri where it is duly licensed to conduct business. In 1993, Glaxo Wellcome, plc formed a joint venture with Warner-Lambert, Inc. to develop and obtain OTC approval for Zantac. OTC approval was obtained in 1995. In 1997, Warner-Lambert and Glaxo Wellcome ended their joint venture and Warner-Lambert retained control over the OTC NDA for Zantac and the Zantac trademark in the U. S. while Glaxo Wellcome retained control over the Zantac trademark internationally. In 2000, Warner-Lambert was acquired by Pfizer, which maintained control over the Zantac OTC NDA until December 2006. Defendant Pfizer may be served by serving its registered agent C T Corporation System, 120 South Central Avenue, Clayton, MO 63105.

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

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

JURISDICTION AND VENUE

19. 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 Plaintiffs are citizens of a state different from any Defendant.

20. Venue is proper in this 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 Missouri and this District and a substantial part of the events giving rise to this action occurred within this District. Venue is proper in the Southeastern Division in that Plaintiffs were injured in Perry County, Missouri where they reside.

FACTUAL ALLEGATIONS

I. A Brief History of Zantac and Ranitidine

21. Zantac was developed by Glaxo – now known as GlaxoSmithKline, 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 (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.

22. 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 sale of $3.98 billion. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year. 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. As one 1996 article put it, Zantac became "the best-selling drug in history as a result of shrewd, multifaceted marketing strategy that…enabled the product to dominate the acid/peptic marketplace."[1] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

23. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year.

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

25. 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.

26. 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 the removal of Zantac and ranitidine products from their shelves.

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[1] Wright, R., *How Zantac Became the Best-Selling Drug in History*, 16 (4) J. HEALTHCARE MARKETING 4, 24 (Winter 1996).

27. 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

28. 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.

29. 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

30. 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 no longer produced or commercially used in the United States, except for the purpose of inducing tumors in laboratory animals. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[2]

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

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

32. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines had been recalled by manufacturers, either voluntarily or at the direction of the FDA.

33. Beginning in July 2018, the FDA 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 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.

34. 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.

35. Alarmingly, Zantac is listed in the FDA's category B 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.

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

37. 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).

38. 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.[3]

39. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researcher noted that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[4]

40. 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

[3] 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).

[4] 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).

exposure and colorectal cancer[5]

III. How Ranitidine Transforms into NDMA Within the Body

41. 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 group 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.

42. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.[6] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[7]

43. Valisure, LLC is an online pharmacy that also runs an analytical laboratory that is accredited by the International Organization for Standardization ("ISO") as ISO 17025, an accreditation recognizing the laboratory's technical competence. 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,

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[5] 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).

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

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

Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

44. Every lot of Zantac and other ranitidine product tested by Valisure revealed exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used the 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.[8] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

45. Valisure's testing detected over 2 million nanograms of NDMA in a single 150 mg Zantac pill. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA more than ***20,000 times*** the permissible limit. In terms of smoking a person would need to smoke at least 6,200 cigarettes to achieve the same level of NDMA found in one 150 mg dose of Zantac.

46. 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 food like processed meats and is elevated in the stomach by antacid drugs.

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

47. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[9]

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

49. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, in amounts far in excess the FDA-allowable limit.

50. 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.

51. 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.

52. 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

[9] See, e.g., https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSU1Eg; https://youtu.be/qvh9gyWqQns.

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

53. 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 separated from the stomach.

54. 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 and 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, dimethylamine [NDMA]."[10]

55. 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")

56. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of DDAH-1 gene is useful for identifying organs most susceptible to this action.

57. DDAH-1 most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, stomach, bladder, brain, colon, and prostate. This offers

[10] 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).

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.

58. 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.[11]

59. 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.[12] 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 the "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers." Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk." NDMA is among the most common of the N-Nitrosamines.

60. 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

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

[12] 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).

for cimetidine administered with nitrite, but ranitidine administered with nitrite resulted in a significant DNA fragmentation.[13]

61. 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 about the NDMA defect but failed to warn or test.

62. During the time the 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.

63. Going back as far as 1981, two years *before* Zantac entered the market, research showed elevated rates of NDMA with the use of ranitidine. This was known or should have been known by the Defendants.

64. 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.

65. Manufacturers of an approved drug are required by regulations 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):

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[13] 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: Live Sciences), Vol. 52. Springer, Boston, MA (1982).

> 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.

66. "The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animals 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).

67. 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.

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

69. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[14] 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.

70. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GKS published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds[15] This study specifically indicated

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[14] Carey et al, *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography,* 225 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

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

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 the 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.

71. 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

72. Plaintiff George White began using Zantac in the mid-1990s, first in prescription form and later OTC. He continued to use Zantac on a regular basis through October 2019.

73. In October of 2019, Plaintiff George White was diagnosed with esophageal and stomach cancer.

74. Based on prevailing scientific evidence, exposure to Zantac (and the attendant NDMA) is known to cause esophageal and stomach cancer in humans.

75. Plaintiff George White's esophageal and stomach cancer were caused by ingestion of Zantac.

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

VI. Damages Allegations

77. As a direct and proximate result of Defendants' carelessness and negligence, the defective nature of their Zantac products and their failure to warn of its dangers, Plaintiff George White suffered severe and permanent physical and emotional injuries, including, but not limited to esophageal and stomach cancer resulting in the complete removal of his stomach. Plaintiff George White has endured pain and suffering, has suffered economic loss, including but not limited to significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff George White has suffered from restrictions in his daily activities and has been deprived of the enjoyment of daily living.

78. Defendants' conduct as alleged herein was willful, wanton and malicious and undertaken with reckless disregard for human life. Prior to and after placing Zantac in to the stream of commerce, Defendants were fully aware of the safety risks of Zantac, particularly the carcinogenic potential of Zantac as it transforms into NDMA within the chemical environment of the human body. Nonetheless, Defendants deliberately crafted their labels, marketing and promotions to mislead consumers into believing that Zantac was safe for human consumption.

79. This was not done by accident or through some justifiable negligence. Rather, Defendants knew that they could turn a profit by convincing consumers that Zantac was harmless to humans and that full disclosure of the true risks of Zantac would limit the amount of money Defendants would make selling Zantac. Defendants' object was accomplished not only through misleading labels, but through a comprehensive scheme of selective misleading research and testing, false advertising and deceptive omissions as more fully alleged throughout this Complaint. Plaintiff George White was denied the right to make an informed decision about whether to purchase and use Zantac, knowing the full risks attendant to that decision. Such

conduct was willful, wanton malicious and exhibits a conscious disregard for the rights and welfare of Plaintiff George White.

80. Accordingly, Plaintiffs request compensatory and punitive damages against Defendants for the harms caused to Plaintiffs.

COUNT I
[Strict Liability – Design Defect]

81. Plaintiff George White re-alleges all prior paragraphs of the Complaint as if set out here full.

82. Plaintiff George White brings this strict liability claim against Defendants for defective design.

83. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing and promoting Zantac products which are defective and unreasonably dangerous to consumers in this District and throughout the United States, including Plaintiff George White, thereby placing Zantac products into the stream of commerce. These actions were done under the ultimate control and supervision of the Defendants.

84. Missouri law requires manufacturers to design reasonably safe products. Defendants had a duty to use reasonable care to design a product that was reasonably safe for its intended use and to prevent defects that constitute a substantial risk of foreseeable injury to persons using such products. Moreover, manufacturers stand in superior position over consumers with regard to knowledge of or the ability to discover and prevent defects.

85. Zantac is defective in design and/or formulation due to its inherent risk 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 group and a dimethylamine ("DMA") group that combine to form a known carcinogen (NDMA), which can lead to the development of cancer.

86. At all relevant times, Defendants' Zantac products were manufactured, designed, and labeled in an unsafe, defective and inherently dangerous manner that posed a risk of serious harm to the public generally and to Plaintiff George White, specifically.

87. Defendants had a duty to use due care in the designing and formulating 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. Missouri 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.

88. The defect in design and/or formulation existed at the time the drug left Defendants' possession and at the time it was sold to Plaintiff George White.

89. Zantac was expected to and did reach Plaintiff George White without a substantial change in the condition in which it was sold.

90. Due to the Defendants' suppression or obfuscation of scientific information linking Zantac to cancer, 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 its use, including the risk of developing cancer.

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

92. As a direct and proximate result of Plaintiff George White's ingestion of Zantac, he developed esophageal and stomach cancer and sustained other damage as previously alleged herein.

93. Defendants were aware of the probable serious consequences of ingesting their product at the time they placed Zantac into the stream of commerce. Despite the fact that Defendants knew or should have known that Zantac caused serious injuries, they failed to exercise reasonable care in the design and distribution of Zantac. Defendants willfully and deliberately hid the serious side effects of their product and failed to disclose these known dangers to the FDA and in doing so acted recklessly and with conscious disregard for the safety of Plaintiff George White.

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

COUNT II
[Strict Liability – Failure to Warn]

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

95. Plaintiff George White brings this strict liability claim against Defendants for failure to warn.

96. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing and promoting Zantac products which are defective and unreasonably dangerous to consumers. Defendants' Zantac products have caused serious harm in this District and throughout the United States, to unsuspecting consumers, including Plaintiff George White. Through their actions, Defendants knowingly and intentionally placed their Zantac products into the stream of commerce in this District and

elsewhere. Defendants' Zantac products were defective and unreasonably dangerous because they did not contain adequate warnings or instructions concerning the dangerous characteristics of Zantac and NDMA. These actions and inactions took place under the ultimate control and supervision of the Defendants.

97. At all times relevant, the Defendants had a duty to warn Plaintiff George White and other consumers about the risks attendant with ingesting their products, including the risk of cancer.

98. Defendants did in fact sell, distribute, supply, manufacture, and /or promote Zantac to Plaintiff George White and to his 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 in this District, including Plaintiff George White and his prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

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

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

101. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, and 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.

102. At the time their Zantac products were placed in the stream of commerce, up to and including the date they were removed from pharmacy shelves in the United States, the Defendants could have provided warnings or given instructions regarding the full and complete dangers of Zantac products because they knew or should have known of the unreasonable risk of harm associated with the use of said products.

103. At all relevant times, Defendants failed and deliberately refused to investigate, study, test or promote the safety of or to minimize the dangers to users and consumers of their Zantac products to those who would foreseeably use or be harmed by them, including Plaintiff, George White.

104. 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.

105. 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.

106. Defendants were aware of the probable consequences of the aforesaid conduct at the time they placed Zantac into the stream of commerce. 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 recklessly and with a conscious disregard for the safety of Plaintiff George White.

107. Plaintiff George White could not have discovered any defect in the dangerous Zantac products though the exercise of reasonable care.

108. Defendants, as the manufacturers and/or distributors of Zantac products, are held to the level of knowledge of an expert in the field.

109. Plaintiff George White reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

110. Had Defendants properly disclosed and warned of the risks associated with Zantac, including cancer, Plaintiff George White would not have used Zantac.

111. 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 previously alleged herein.

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

COUNT III
[Negligence]

112. Plaintiff George White realleges all prior paragraphs of the Complaint as if set out here in full.

113. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff George White, in the design, development, manufacture, marketing, advertisement, supply, promotion, marketing distribution, labeling, and/or sale of Zantac such that their product was not unreasonably dangerous to consumers.

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

115. Plaintiff George White'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 George White of Zantac's dangerous and defective characteristics;

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

d) In promoting Zantac in an overly aggressive, deceitful, and fraudulent manner, despite evidence of 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 George White and his healthcare provider that the use of Zantac carried a risk of developing cancer;

k) In failing to provide adequate post-marketing warnings or instructions after Defendants 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 George White and the healthcare industry of the risk of serious personal injury, namely cancer, from Zantac ingestion as described herein.

116. Defendants knew or should have known that consumers, such as Plaintiff George White would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

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

118. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiff George White, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to redesign, re-label, warn or inform the unsuspecting public, including Plaintiff George White. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff George White respectfully requests that this Court enter judgment on Count III in his 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]

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

120. 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.

121. 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 and their marketing personnel about the safety of Zantac, which also downplayed the risk associated with the product; and (d) false, misleading, and inadequate written information and packaging supplied by Defendants.

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

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

124. 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.

125. 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.

126. As a direct and proximate result of Defendants' breach of these express warranties, Plaintiff George White suffered serious injuries and/or side effects, including cancer as set forth previously herein.

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

COUNT V
[Breach of Implied Warranty]

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

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

129. Plaintiff George White was a foreseeable user of Zantac.

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

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

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

133. Contrary to Defendants' implied warranties, Zantac is neither of merchantable quality, nor safe or effective for its intended and ordinary use, because the product is unreasonably dangerous, defective, unfit, and ineffective for the ordinary purposes for which it is used.

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

135. In violation of RSMo. Section 400.2-314 and RSMo. Section 400.2-315, Defendants breached their implied warranties 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.

136. Plaintiff George White could not have discovered that Defendants breached these implied warranties and had no reason to believe that there was any danger in using Zantac.

137. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff George White suffered serious injuries and/or side effects, including cancer as described previously herein.

WHEREFORE, Plaintiff George White respectfully requests that this Court enter judgement on Count V in his favor for compensatory and punitive damages, together with interest, costs herein incurred and all such other and further relief as the Court deems just and proper.

COUNT VI
[Negligent Misrepresentation]

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

139. Defendants negligently and/or recklessly misrepresented to Plaintiff George White, his prescribing physicians, and the healthcare industry in general, 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.

140. Defendants made reckless and 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 George White, his physicians and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff George White, his prescribing physicians, the health care industry, and the consuming public:

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 are carcinogenic;

f) the inadequacy of the labeling for Zantac; and

g) the dangerous effects of Zantac.

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

142. 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 the Plaintiff George White, his prescribing physicians, and the healthcare industry.

143. Defendants made these false representations without the exercise of due care and despite knowing that it was reasonable and foreseeable that Plaintiff George White, his prescribing

physicians, and the healthcare industry in general would rely on them, leading to the use of Zantac by Plaintiff George White as well as the general public.

144. At all times herein mentioned, neither Plaintiff George White nor his 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, his physicians would not have prescribed and Plaintiff George White would not have taken Zantac.

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

146. Defendants had a post-sale duty to warn Plaintiff George White, his prescribing physicians and the general public about the potential risk and complications associated with Zantac in a timely manner

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

148. As a direct and proximate result of the foregoing concealments and omissions Plaintiff George White suffered serious injuries as alleged previously herein.

WHEREFORE, Plaintiff George White respectfully requests that this Court enter judgment on Count VI in his 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 VII
[Loss of Consortium]

149. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

150. Plaintiff Carol White, is, and at all times relevant was, the spouse of Plaintiff George White.

151. As a result of the actions and/or omissions of the Defendants set forth above, Plaintiff Carol White, has been deprived of the services, assistance, aid, society, love, affection, companionship, and conjugal relationship of her husband, Plaintiff George White and is entitled to recover for her loss of consortium.

152. The damages of Plaintiff Carol White, exceed the minimum amount required for the jurisdiction of this Court.

153. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish and deter similar conduct in the future.

WHEREFORE, Plaintiff Carol White respectfully requests that the Court enter judgment on Count VII 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.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants as follow:

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 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

Plaintiffs demand a trial by jury on all issues so triable.

Dated: August 26, 2020

Respectfully submitted,

COOK, BARKETT, PONDER & WOLZ, L.C.

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