IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROBIN S. MCKINNEY, 1262 Talbert Street, SE #15A Washington, DC 20020 Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., 900 Ridgebury Road, Ridgefield, Connecticut 06877; SANOFI US SERVICES, INC., 55 Corporate Drive, Bridgewater, New Jersey 08807; CHATTEM, INC., 1715 West 38th Street, Chattanooga, Tennessee 37409; PFIZER, INC., 235 East 42nd Street, New York, New York 10017; and GLAXOSMITHKLINE, LLC, 5 Crescent Drive, Philadelphia, Pennsylvania 19112, Defendants.	Case No. 1:20-CV-646 COMPLAINT DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, by and through undersigned counsel, hereby brings this Complaint for damages against Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"); Sanofi US Services Inc. ("Sanofi"); Chattem Inc. ("Chattem); Pfizer, Inc. ("Pfizer"); and Glaxosmithkline, LLC ("GSK"), and alleges as follows:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a director and proximate result of the Sanofi's and Boehringer's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, marketing, advertising, promoting, labeling, distribution and/or sale of the drug Zantac. Plaintiff alleges that Zantac is defective, dangerous to human health, and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.
2. Plaintiff Robin S. McKinney took Zantac almost daily for 18 years and, as a result, was diagnosed with kidney cancer and had her gall bladder removed in 2019. Plaintiff's kidney cancer and gall bladder removal were caused by NDMA exposure due to plaintiff's daily ingestion of Zantac.
3. N-Nitros28odimethylamine ("NDMA") is a potent carcinogen. It is used to induce cancerous tumors in laboratory animals. It is also occurring in substantially high levels in a popular antacid medication, popularly known as Zantac.
4. 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 it is digested by the human body. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 ng (nanograms) and yet, in a single dose of Zantac, researchers are discovering over 3 million ng.
5. These recent revelations by independent researchers have caused widespread recalls of Zantac both domestically and internationally, and the FDA is actively investigating the issue, with is preliminary results showing "unacceptable" levels of NDMA. Indeed, the current

owner and controller of the Zantac new drug applications ("NDAs") has recalled all Zantac in the United States.

PARTIES

6. Plaintiff Robin S. McKinney is a natural person and at all relevant times a resident of the District of Columbia. Plaintiff brings this action for personal injuries sustained by the use of Zantac. Plaintiff regularly ingested Zantac since 2002, ingesting the drug 5-7 times a week on average. Plaintiff was initially prescribed Zantac by her physician and subsequently ingested over-the-counter ("OTC") Zantac (collectively referred to hereafter as "Zantac"). As a direct and proximate result of ingesting Zantac, Plaintiff developed kidney cancer and painful gall bladder stones and complications and underwent surgery in 2018 to have half of her left kidney and gall bladder removed.

7. Defendant Boehringer 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 Delaware, and not of any other state. Boehringer is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned and controlled the new drug applications ("NDA") for OTC Zantac between December 2006 and January 2017, and manufactured and distributed the drug in the United States during that period.

8. 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. Sanofi controlled the NDA for OTC Zantac starting in January 2017 through the present and manufactured and

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

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

11. Defendant Pfizer is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer is a citizen of Delaware and New York and is not a citizen of any other state. In 1993, Glaxo Wellcome, plc formed a joint venture with Warner-Lambert, Inc. to develop and obtain OTC approval for Zantac. That OTC approval was obtained in 1995. In 1997, Warner-Lambert and Glaxo Wellcome ended their joint venture, with Warner-Lambert retaining control over the OTC NDA for Zantac and the Zantac trademark in the U.S. and Glaxo Welcome retaining control over the Zantac trademark internationally. In 2000, Warner-Lambert was acquired by Pfizer, who maintained control over the Zantac OTC NDA until December 2006.

12. Defendant GSK is a Delaware company with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112 and Five Moore Drive, Research

Triangle, North Carolina, 27709. GSK is a wholly owned subsidiary of GlaxoSmithKline, plc, which is its sole member. GlaxoSmithKline, plc is a citizen of the United Kingdom, and is not a citizen of any state in the United States. GlaxoSmithKline plc is the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known as ranitidine. Ranitidine was initially developed by Allen & Hanburys Ltd., which was a subsidiary of Glaxo Labs Ltd. Allen & Hanburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule. In 1983, Glaxo Holdings, Ltd. was awarded approval by the U.S.FDA to sell Zantac in the United States. Glaxo Holdings, Ltd. was later absorbed into Glaxo Wellcome, plc. And then, in 2000, GlaxoSmithKline, plc and GSK were created by the merger of Glaxo Wellcome and SmithKline Beecham. GSK, and its predecessors, controlled the prescription Zantac NDA between 1983 and 2009. Under California law, GSK is the innovator of Zantac and, through its negligence and willful misconduct, caused the labeling on the OTC Zantac label to not include any warning for cancer.

JURISDICTION AND VENUE

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

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

15. 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 sell, market and/or distribute Zantac within the District of Columbia.

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. 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.

17. Due in large part to GSK's marketing strategy, Zantac was a very successful drug. By the end of 1986, it had reached $1 billion in sales. By 1988, it was the world's best-selling drug and in June 1989, Zantac made up over half of Glaxo's sales of nearly $4 billion. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sale of Zantac 150 totaling $128.9 million.

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

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

20. 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.

21. On September 28, 2019, CVS Health Corp. stated that it would stop selling Zantac and its own generic ranitidine products out of concern that it might contain a carcinogen. CVS has been followed by Walmart, Inc., Walgreens Boot Alliance, and Rite Aid Corp. to also remove Zantac and ranitidine products.
22. On October 2, 2019, the FDA stated that it was ordering all manufacturers of Zantac and ranitidine products to conduct testing for NDMA and that preliminary results indicted unacceptable levels of NDMA.
23. 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.
24. 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 not have rejected it.

B. The Dangers of NDMA

25. 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 research, such as inducing tumors in laboratory animals.
26. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen. And 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.

27. Beginning in July 2018, the FDA has recalled several generic blood pressure medications, such as: valsartan, losartan, and irbesartan, because the medications contained nitrosamine impurities that exceeded the 96 nanogram acceptable daily threshold set by the FDA. The highest levels detected by the FDA in valsartan pills were over 20,000 nanograms per pill. In the case of Valsartan, NDMA was deposited into the pill due to a manufacturing defect, and therefore, NDMA was present in only some of the valsartan containing products. For Zantac, NDMA is a byproduct of the ranitidine molecule itself, and the levels observed in recent testing show NDMA levels in excess of 3,000,000 nanograms. In addition, NDMA has been a byproduct of the ranitidine molecule since it was first marketed in the U.S. in 1983. Therefore, Zantac consumers will have been exposed to millions of nanograms of NDMA from 1983 until Zantac was recently pulled off the pharmacy shelves.
28. 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.
29. Alarmingly, Zantac is listed in FDA's category for birth defects, meaning it is considered safe to take during pregnancy. However, in laboratory animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.
30. Numerous in vitro studies confirm that NDMA is a mutagen that causes mutations in human and animal cells.
31. 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).

32. 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.[1]

33. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.[2]

34. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.[3]

35. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[4]

36. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was

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[1] 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).
[2] La Vecchia et al, *Nitrosamine intake and gastric cancer risk,* 4 EUROP. J. CANCER. PREV. 469–474 (1995).
[3] Rogers et al, *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer*, 5 CANCER EPIDEMIOL. BIOMARKERS PREV. 29–36 (1995).
[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).

significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[5]

37. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[6]

C. How Ranitidine Transforms into NDMA Within the Body

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

39. 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.[7] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[8]

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[5] Loh et al, *N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study,* 93 AM J CLIN NUTR. 1053–61 (2011).
[6] 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).
[7] 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).
[8] Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).

40. Recent testing of NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

41. Valisure, LLC is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

42. As part of its testing of Zantac, and other ranitidine products, in every lot tested, Valisure discovered exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[9] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

43. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at 28,000 times the legal limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

44. To be sure that the extremely high levels of NDMA observed in its testing were not the result of an FDA recommended GC/MS protocol that required an oven heating parameter of 130

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

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

45. Valisure also tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs.

46. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[10]

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

48. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit.

49. 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

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

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

50. 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.

51. Existing research shows that ranitidine interacts with nitrites and acids in the chemical environment of the human stomach to form NDMA. In vitro tests demonstrate that when ranitidine undergoes "nitrosation" (the process of a compound being converted into nitroso derivatives) by interacting with gastric fluids in the human stomach, the by-product created is dimethylamine ("DMA") – which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

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

53. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge

for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[11]

54. 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").

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

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

57. 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.[12]

[11] Ogawa et al, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 J. BIO. CHEM. 17, 10205-10209 (1989).
[12] Zeng et al, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine,* 37 CARCINOGENESIS 625-634 (2016).

58. 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.[13] One of the variables investigated by the authors was the patients' consumption of a prescription antacid, either Tagamet (cimetidine) or Zantac (ranitidine). The authors concluded that "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers." Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk." NDMA is among the most common of the N-Nitrosamines.

59. A 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, no effect was observed for cimetidine administered with nitrite, but ranitidine administered with nitrite resulted in a significant DNA fragmentation.[14]

60. 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[.]"

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[13] 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).

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

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

61. During the time that Defendants manufactured and sold Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and Defendants failed to report these risks to the FDA.

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

63. 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.

64. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

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

66. 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.

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

68. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[15] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiff believes this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product.

69. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[16] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by

[15] Carey et al*, Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).
[16] Thomas et al, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 GUT. Vol. 28, 726-738 (1987).

design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk.

70. 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).

E. Plaintiff's Specific Allegations

71. Plaintiff began using Zantac in approximately 2002 and used it through September 2019. She took it 5-7 times a week.

72. In 2018, Plaintiff was diagnosed with kidney cancer and had her gall bladder removed.

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

74. Plaintiff's kidney cancer and gall bladder complications resulting in gall bladder removal were caused by ingestion of Zantac.

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

76. Plaintiff did not learn of the link between her cancer and gall bladder removal and Zantac exposure until September 30, 2019, when she learned that Zantac contained high levels of NDMA by watching the news.

COUNT I
Strict Liability-Design Defect

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

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

79. 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, including Plaintiff, thereby placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the Zantac products used by Plaintiff, as described herein.

80. At all relevant times, Defendants' Zantac products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, including Plaintiff.

81. At all relevant times, Defendants' Zantac products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed and sold Zantac products within this judicial district and aimed at a consumer market within this judicial district. Defendants were at all relevant times involved in the retail and promotion of Zantac products marketed and sold in this judicial district.

82. Defendants' Zantac products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the control of Defendants' manufacturers and/or suppliers, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

83. Defendants' Zantac products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

84. At all relevant times, Defendants knew or had reason to know that Zantac products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

85. Therefore, at all relevant times, Defendants' Zantac products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

    a. When placed in the stream of commerce, Defendants' Zantac products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

    b. When placed in the stream of commerce, Defendants' Zantac products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

    c. When placed in the stream of commerce, Defendants' Zantac products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Defendants did not sufficiently test, investigate, or study its Zantac products and, specifically, the ability for Zantac to transform into the carcinogenic compound NDMA within the human body;

e. Exposure to Zantac products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

f. Defendants knew or should have known at the time of marketing Zantac products that exposure to Zantac could result in cancer and other severe illnesses and injuries;

g. Defendants did not conduct adequate post-marketing surveillance of its Zantac products; and

h. Defendants could have employed safer alternative designs and formulations.

86. Plaintiff used and was exposed to Defendants' Zantac products without knowledge of Zantac's dangerous characteristics.

87. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendants' Zantac products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

88. Plaintiff could not reasonably have discovered the defects and risks associated with Zantac products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Zantac to cancer.

89. The harm caused by Defendants' Zantac products far outweighed their benefit, rendering Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Zantac products were and are more dangerous than alternative products, and Defendants could have designed Zantac products to make them less dangerous. Indeed, at the time Defendants designed Zantac products, the state of the industry's scientific

knowledge was such that a less risky design or formulation was attainable. At the time Zantac products left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Zantac products. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.[17]

90. Defendants' defective design of Zantac products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Zantac products, including Plaintiff.

91. Therefore, as a result of the unreasonably dangerous condition of their Zantac products, Defendants are strictly liable to Plaintiff.

92. he defects in Defendants' Zantac products were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendants' misconduct and omissions, Plaintiff would not have sustained injuries.

93. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of its products, including Plaintiff, with knowledge of the safety problems associated with Zantac products, and suppressed this knowledge from the general

[17] *See, e.g.*, Vermeer, et al., *Effect of ascorbic acid and green tea on endogenous formation of N nitrosodimethylamine and N-nitrosopiperidine in humans*. 428 MUTAT. RES., FUNDAM. MOL. MECH. MUTAGEN. 353–361 (1999); Garland et al., *Urinary excretion of nitrosodimethylamine and nitrosoproline in humans: Interindividual and intraindividual differences and the effect of administered ascorbic acid and α-tocopherol*, 46 CANCER RESEARCH 5392–5400 (1986).

public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

94. As a direct and proximate result of Defendants placing its defective Zantac products into the stream of commerce, and the resulting injuries, Plaintiff sustained pecuniary loss including general damages in a sum which exceeds the jurisdictional minimum of this Court.

95. As a proximate result of Defendants placing its defective Zantac products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff has suffered great mental anguish and other personal injury and damages.

96. As a proximate result of the Defendants placing its defective Zantac products into the stream of commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

97. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's 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.

COUNT II
Strict Liability-Failure to Warn

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

99. 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.

100. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Zantac to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the Zantac that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and

Zantac did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

101. 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.

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

103. 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.

104. 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.

105. 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.

106. 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.

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

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

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

110. Had Defendants properly disclosed the risks associated with Zantac, including cancer or organ removal, Plaintiff 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 herein alleged.

112. 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

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

114. 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.

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

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

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

b. In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Zantac's dangerous and defective characteristics;

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

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

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

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

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

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

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

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

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

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

117. 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.

118. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, kidney cancer and gall bladder removal. 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.

119. 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 Warranties

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

121. 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, including Plaintiff, thereby

placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

122. 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.

123. These warranties came in one or more of the following forms:

a. publicly made written and verbal assurances of safety;

b. press releases, media dissemination, or uniform promotional information intended to create demand for Zantac, but which contained misrepresentations and failed to warn of the risks of using the product;

c. verbal assurances made by Defendants' marketing personnel about the safety of Zantac, which also downplayed the risks associated with the product; and

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

124. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Zantac products, including a duty to:

a. ensure that its products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Zantac, when making representations to consumers and the general public, including Plaintiff.

125. At all relevant times, Defendants expressly represented and warranted to the

126. purchasers of its products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Zantac products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted Zantac products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Zantac products would conform to the representations.

127. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Zantac. Defendants knew and/or should have known that the risks expressly included in Zantac warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that Zantac products were safe and effective, that they were safe and effective for use by individuals such as the Plaintiff, and/or that they were safe and effective as consumer medication.

128. The representations about Zantac, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

129. Defendants placed Zantac products into the stream of commerce for sale and recommended their use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Zantac.

130. Defendants breached these warranties because, among other things, Zantac products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through its labeling, advertising, and marketing materials that Zantac products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Zantac and by expressly limiting the risks associated with use within its warnings and labels; and

b. Defendants represented that Zantac products were safe for use and intentionally concealed information that demonstrated that Zantac, by transforming into NDMA upon human ingestion, had carcinogenic properties, and that Zantac products, therefore, were not safer than alternatives available on the market.

131. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Zantac in deciding to purchase the product. Plaintiff reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Zantac. Plaintiff would not have purchased or used Zantac had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

132. Defendants had sole access to material facts concerning the nature of the risks associated with its Zantac products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Zantac warnings and labels were inadequate and inaccurate.

133. Plaintiff had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Zantac.

134. Plaintiff used and/or was exposed to Zantac as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

135. Had the warnings, labels, advertisements, or promotional material for Zantac products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiff could have avoided the injuries complained of herein.

136. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

137. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

138. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

139. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's 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.

COUNT V
Breach of Implied Warranties

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

141. 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, including Plaintiff, thereby placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

142. Before the time Plaintiff used Zantac products, Defendants impliedly warranted to its consumers, including Plaintiff, that Zantac products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

143. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers, such as Plaintiff, of its Zantac products.

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

145. 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.

146. 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.

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

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

149. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Zantac.

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

151. 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.

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

153. 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

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

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

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

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

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

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

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

e. that harmful levels of NDMA is carcinogenic;

f. the inadequacy of the labeling for Zantac; and

g. the dangerous effects of Zantac.

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

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

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

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

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

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

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

164. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff suffered serious injuries, including cancer and gall bladder removal.

165. 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.

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

167. 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.

PRAYER FOR RELIEF

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

a. Actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. Exemplary and punitive damages sufficient to punish and deter the Defendants and others form future wrongful practices;

c. Pre-judgement and post-judgment interest;

d. Costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

e. Any other relief the Court may deem just and proper.

Respectfully submitted,

[redacted]

[redacted]

JURY TRIAL DEMAND

Plaintiff requests a jury trial on all counts.

[redacted]