IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO.

KATHRIN DAVIS,

Plaintiff,

vs.

COMPLAINT

JURY TRIAL DEMANDED

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

Defendants.
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INTRODUCTION

1. Nitrosodimethylamine ("NDMA") is a potent carcinogen. It used to be a chemical biproduct of making rocket fuel in the early 1900's but, today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer and it has no business being in a human body.

2. This case involves perhaps one of the most sinister public-health frauds of modern times. 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. This occurs through the process of nitrosation, wherein the ranitidine interacts with nitrites in the chemical environment of the stomach to form NDMA.

3. 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, independent researchers are discovering over 3 million ng.

4. 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.

5. To be clear, this is not a contamination case—the levels of NDMA that researchers are seeing in Zantac is not the product of some manufacturing error. The high levels of NDMA observed in Zantac is a function of the ranitidine molecule and the way it breaks down in the human digestive system.

6. Each Defendant knew or should have known at all times it sold Zantac that the drug has the critical and deleterious defect of producing high quantities of NDMA in the human body when ingested. The dangers of NDMA have been publicly known for over 40 years, well before Zantac hit the market.

7. Moreover, during the period that Defendants manufactured and distributed Zantac, numerous scientific studies were published showing, among other things, that ranitidine (the generic bioequivalent of Zantac) forms NDMA when placed in drinking water, and that a person who consumes ranitidine has a 400-fold increase of NDMA concentration in their urine.

8. Despite the weight of scientific evidence showing that Zantac exposed users to unsafe levels of the carcinogen NDMA, no Defendant ever disclosed this risk to the FDA, on the drug label, or through any other means.

9. Had Defendants disclosed that Zantac results in unsafe levels of NDMA in the human body, no person, let alone a reasonable person, would have consumed Zantac (or its generic

equivalent). Indeed, had Defendants complied with their federal regulatory reporting requirements, the FDA would never have approved Zantac as being safe.

10. Instead, Defendants put profits over safety and aggressively pushed a dangerous drug into the marketplace. Through Defendants' marketing efforts, which touted the purported safety of the drug, Zantac became one of the best-selling drugs in history when, in reality, every single dose of Zantac produces levels of NDMA in the human body when ingested that exceed the FDA's permissible daily limits for the carcinogen by thousands of times.

PARTIES

11. Plaintiff Kathrin Davis (hereinafter "Plaintiff") regularly took Zantac for decades and, as a result, developed colon cancer. Mrs. Davis' cancer was caused by NDMA exposure created by the ingestion of Zantac. This lawsuit seeks damages against the Defendants for causing her cancer.

12. Plaintiff resides in Port St. Lucie, Martin County, Florida.

13. Defendant GlaxoSmithKline plc is an English corporation with its principal place of business at 980 Great West Road, Brentford, Middlesex, England.

14. Defendant GlaxoSmithKline LLC 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, and is a wholly-owned subsidiary of GlaxoSmithKline, plc.

15. GlaxoSmithKline plc (as the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known a ranitidine) and GlaxoSmithKline LLC (collectively "Glaxo") were the sole manufacturer of prescription Zantac throughout the United States from 1983 through 1996. Beginning in 1996, Glaxo also sold over-the-counter

versions of Zantac in the United States for a limited time and continued to sell the prescription version of Zantac in the United States until recently.

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. From approximately 1996 or 1997 through December 2006, Pfizer (initially through non-party Warner-Lambert, which Pfizer acquired in 2000) owned the rights to manufacture, market, and sell over-the-counter Zantac throughout the United States, and did manufacture, market, and sell over-the-counter Zantac throughout the United States during that period.

17. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Between December 2006 and January 2017, BI owned the rights to manufacture, market, and sell over-the-counter Zantac in the United States, and did manufacture, market and sell over-the-counter Zantac in the United States during that period.

18. Defendant Sanofi S.A. is a French multinational pharmaceutical company with its principal place of business located at 54, Rue La Boetie in the 8th arrondissement.

19. Defendant Sanofi US Services, Inc., is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly-owned subsidiary of Sanofi S.A.

20. Defendant Sanofi-Aventis U.S. LLC is a Delaware company 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.

21. Defendant Chattem, Inc. is a Tennessee corporation with its principal place of business located at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly-owned subsidiary of Sanofi S.A., a French multinational corporation.

22. Defendants Sanofi S.A., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC and Chattem, Inc. (collectively "Sanofi") have owned the rights to manufacture, market and sell over-the-counter Zantac in the United States since January 2017, and did manufacture, market and sell over-the-counter Zantac in the United States until recently.

JURISDICTION AND VENUE

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

24. This Court has personal jurisdiction over each Defendant because each Defendant maintains and carries on systematic and continuous contacts in this judicial district, and regularly avails itself of the benefits of this judicial district. Additionally, this Court has personal jurisdiction over each Defendant because each Defendant caused tortious injury by acts and omissions in this judicial district, and because each Defendant caused tortious injury in this judicial district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

25. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because each Defendant transacts business in, is found in, and/or has agents in this district, and because a substantial part of the events or omissions giving rise to this claim occurred within this judicial district.

FACTUAL ALLEGATIONS

A. Brief History of Zantac and Ranitidine

26. The ranitidine molecule was discovered in 1976 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. Ranitidine was specifically developed in response to the then leading H2 blocker, cimetidine (Tagamet).

27. Zantac was a wildly successful drug, reaching $1 billion in sales in the first three alone. As one 1996 article put it, "Zantac became "the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that . . . enabled the product to dominate the acid/peptic marketplace."[1]

28. But Zantac's unprecedented sales were possible only because of a deception perpetrated by all manufacturers since the drug hit the U.S. market in 1983. Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

29. However, even at the time that ranitidine was developed, there was already existing scientific literature suggesting that drugs like ranitidine are highly likely to form NDMA when combined with other substances, like nitrite, found in the body.

30. The scientific evidence regarding the dangers of NDMA and how ranitidine transforms into NDMA in the human body only mounted in the ensuing years, yet Defendants

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

continued to aggressively market the product as safe and failed to warn consumers (or the FDA, for that matter) of its inherent dangers.

31. Indeed, Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year. Although sales of brand-name Zantac declined as a result of generic and alternative products, Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

32. Zantac is used not only by adults but it is also given to children and teenagers to treat gastroesophageal reflux disease, among other things. Further, Zantac is often used by pregnant women to treat pregnancy-related heartburn symptoms; thus, not only is the pregnant woman exposed to NDMA, but her fetus is also exposed to this carcinogenic compound.

33. Recently, Valisure LLC ("Valisure"), an independent pharmacy, confirmed in a series of rigorous scientific tests that Zantac forms NDMA. Valisure is an online pharmacy that also runs an analytical laboratory. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market.

34. In its recent tests, Valisure "detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products," including Zantac.[2]

35. Valisure notified the FDA or its findings by filing a Citizen Petition in September 2019.[3] In addition, Valisure submitted a copy of the Citizen Petition to the World Health

[2] Valisure Citizen Petition, p.6, *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (last visited April 9, 2020).
[3] Valisure Citizen Petition, *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (last visited April 9, 2020).

Organization, and to the International Agency for the Research of Cancer to have ranitidine classified as a human carcinogen.

36. When the news of the Valisure Citizen Petition broke on September 13, 2019 that Zantac exposed users the NDMA, "[g]lobal health regulators sounded a coordinated alarm."[4] In response, both U.S. and European regulators stated that they are reviewing the safety of ranitidine.

37. In the U.S., many pharmacies and ranitidine manufacturers themselves (including Defendants Glaxo and Sanofi) have pulled Zantac from their shelves or have recalled their products.

38. 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 indicated unacceptable levels of NDMA so far.

39. In addition, in dozens of countries spanning the globe, regulators have issued recalls, medical alerts, and announced investigations, or companies have voluntarily recalled their Zantac and/or generic ranitidine products.

40. At no time did any Defendants 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 over-the-counter) 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 over-the-counter), the FDA would not have rejected it.

[4] Anna Edney & John Lauerman, *Carcinogen in Zantac and its generics triggers probes by FDA, EU*, THE HAMILTON SPECTATOR (Sept. 13, 2019), *available at* https://www.thespec.com/business/2019/09/13/carcinogen-in-zantac-and-its-generics-triggers-probes-by-fda-eu.html (last visited April 9, 2020).

B. Dangers of NDMA

41. 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.

42. The dangers that NDMA poses to human health have long been recognized. As early as 1979, a news article noted that NDMA had caused cancer in nearly every laboratory animal tested so far.

43. NDMA is no longer produced or commercially used in the United States, except for research, such as a tumor initiator in certain animal bioassays. In other words, it is only a poison.

44. Both the Environmental Protection Agency and the International Agency for Research on Cancer have classified NDMA as a probable human carcinogen. And the World Health Organization 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.

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

46. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—valsartan, losartan, and irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

47. The FDA has established a permissible daily intake limit for the probable human carcinogen, NDMA, of 96 ng (nanogram). However, the highest level of NDMA detected by the FDA in any of the Valsartan tablets was 20.19 jig (or 20,190 ng) per tablet. In the case of Valsartan,

the NDMA was an impurity caused by a manufacturing defect, and thus NDMA was present in only some products containing valsartan.

48. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Not only is NDMA a byproduct of the ranitidine molecule itself, but the levels observed in recent testing show NDMA levels in excess of 3,000,000 ng.

49. For comparison, tobacco smoke also contains NDMA. One filtered cigarette contains between 5 – 43 ng of NDMA.

50. In studies involving mice where the carcinogenicity of NDMA is examined through oral administration, animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, similar cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, similar cancers were observed in the liver, pancreas, and stomach. In comparable Guinea-pig studies, similar cancers were observed in the liver and lung. In comparable rabbit studies, similar cancers were observed in the liver and lung.

51. In other long-term animal studies in mice and rats utilizing different routes of exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

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

53. In addition, NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon).

54. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing mutations in human and animal cells.

55. Overall the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice, rats, Syrian golden, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, fish, newts, and frogs.

56. Pursuant to the EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[5]

57. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. And, while these studies (several discussed below) consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction—as little as 1 millionth—the exposures noted in a single Zantac capsule, *i.e.*, 0.191 ng/day (dietary) vs. 304,500 ng/day (Zantac).

58. 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.[6]

59. 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.[7]

[5]*See, Guidelines for Carcinogen Risk Assessment* (March 2005), *available at* https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf (last visited April 10, 2020)
[6] 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).
[7] La Vecchia et al, *Nitrosamine intake and gastric cancer risk*, 4 EUROP. J. CANCER. PREV. 469– 474 (1995).

60. 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.[8]

61. 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.[9]

62. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.[10]

63. 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 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.[11]

64. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[12]

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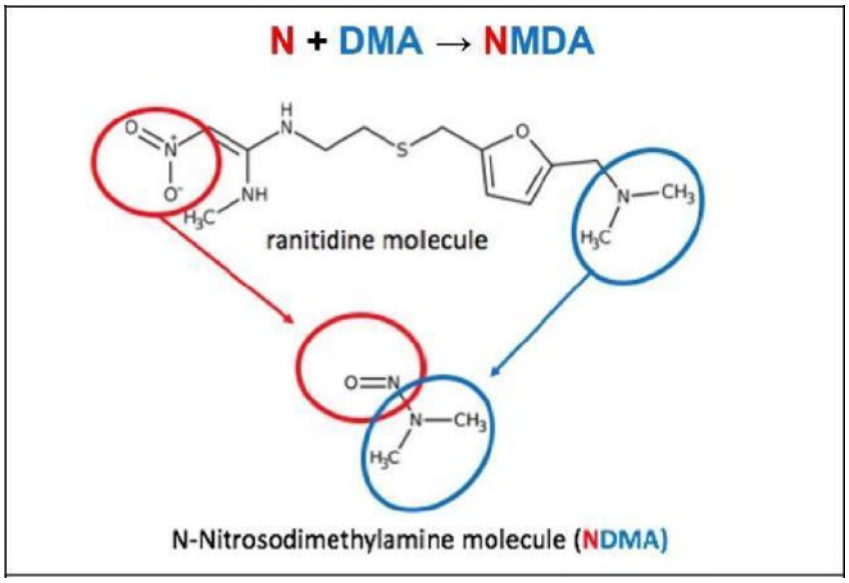
[8] Rogers et al, *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cance*r, 5 CANCER EPIDEMIOL. BIOMARKERS PREV. 29–36 (1995).
[9] Knekt et al, *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 INT. J. CANCER 852–856 (1999).
[10] Straif et al, *Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers*, 57 OCCUP ENVIRON MED 180–187 (2000).
[11] 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).
[12] Zhu et al, *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada*, 111 BR J NUTR. 6, 1109–1117 (2014).

C. How Ranitidine Transforms into NDMA Within the Body

65. 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. *See* Fig. 1. Thus, ranitidine produces NDMA by reacting with itself, which means that every dosage and form of ranitidine, including Zantac, exposes users to NDMA.

Figure 1 –Ranitidine Structure & Formation of NDMA



66. The formation of NDMA by the reaction of DMA and a nitroso source (such as nitrite) was the subject of scientific research even when Zantac was being launched in the early 1980s.

67. In 1981, the very year Zantac became commercially available outside of the U.S., an exchange in The Lancet—one of the most widely read and respected medical and scientific publications—discussed the potential toxicity of cimetidine[13] and ranitidine.

68. Dr. Silvio de Flora, an Italian researcher from the University of Genoa, wrote about experiments he had conducted looking at cimetidine and ranitidine in human gastric fluid.[14] When ranitidine was exposed to gastric fluid in combination of with nitrites, his experiment showed toxic and mutagenic effects. Dr. de Flora hypothesized that these effects could have been caused by the formation of more than one nitroso derivative (which includes NDMA) under the experimental conditions. Concerned with these results, Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals, or by giving inhibitors of nitrosation such as ascorbic acid."

69. Glaxo responded to Dr. de Flora's article and sought to discredit his research.[15] Glaxo cited to a study it had recently performed on ranitidine itself which, despite appearing to be flawed, admittedly detected that a mutagenic product was formed by ranitidine in the presence of nitrites. Glaxo nevertheless dismissed this finding because the levels of nitrate used were allegedly much higher than what would be expected to occur after a meal and thus asserted that "no mutagenic nitrosated product of ranitidine is likely to be formed in man under any conceivable physiological conditions[.]"

70. In 1983, the same year Zantac was approved in the U.S., seven researchers from the University of Genoa published a study discussing the nitrosation of ranitidine and its genotoxic

[13] Cimetidine, also an H2 blocker, has a similar chemical structure to ranitidine.
[14] De Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, THE LANCET (Oct. 31, 1981).
[15] Brittain et al, *The Safety of Ranitidine*, THE LANCET 1119 (Nov. 14, 1981).

effects (ability to harm DNA).[16] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells . . . . These findings are consistent with those of De Flora, who showed that preincubation of ranitidine with excess nitrite in human gastric juice resulted in mutagenic effects[.]"

71. Then, again in 1983, Dr. de Flora, along with four other researchers, published the complete findings.[17] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine[.]" Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals . . . Ascorbic acid has been proposed as an inhibitor of nitrosation combined with nitrosatable drugs and appears to block efficiently the formation of mutagenic derivatives from . . . ranitidine."

72. Also in 1983, another study specifically suspected the carcinogenic nature of ranitidine combination with nitrite.[18] The authors concluded: "Our experimental findings have shown that simultaneous oral administration in rats of high doses of ranitidine and NaNO2 [nitrite] can produce DNA fragmentation either in liver or in gastric mucosa."

73. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) has also been identified as a concern for contamination of the American water supply.[19]

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[16] Maura et al, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LTTRS. 97-102 (1983).
[17] De Flora et al, *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).
[18] Brambilla et al., *Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite*, 4 CARCINOGENESIS 10, 1281-1285 (1983).
[19] 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).

Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[20]

74. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[21] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants which supply many American cities with water.

75. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. 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

76. Most recently, Valisure's testing showed that ranitidine can react with itself at high efficiency to produce NDMA at dangerous levels well in excess of the FDA's permissible 96 ng daily intake limit for this carcinogen.

77. Valisure is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory. In addition, Valisure has developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

[20] Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).
[21] Le Roux et al, *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012).

78. For its testing of Zantac and other ranitidine products, Valisure used the FDA recommended gas chromatography/mass spectrometry ("GC/MS") analysis method for the determination of NDMA levels.[22] The results of Valisure's testing show exceedingly high levels of NDMA in every lot tested; that is, levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

79. 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. By comparison, 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.

80. Valisure, however, was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So, 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.

81. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" and "Simulated Intestinal Fluid" 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.

82. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[23]

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[22] *See* US Food and Drug Administration. (updated 01/28/2019). Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY19-005-DPA-S.*, *available at* https://www.fda.gov/media/117843/download (last visited April 10, 2020).

[23] *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.

83. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are similarly found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit. This is consistent with recent peer-reviewed literature, which has demonstrated the existence of dangerous levels of NDMA in the urine of individuals who have taken ranitidine.[24]

84. Compounding the danger, 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 even present in the warning labels of antacids like Prevacid (lansoprazole) 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.

85. In fact, NDMA formation in the stomach has been a concern for many years and ranitidine specifically has been implicated as a cause of NDMA formation by multiple research groups, including those at Stanford University.

86. 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 by interacting with gastric fluids in the human stomach, the by-product created is DMA – which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA.

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

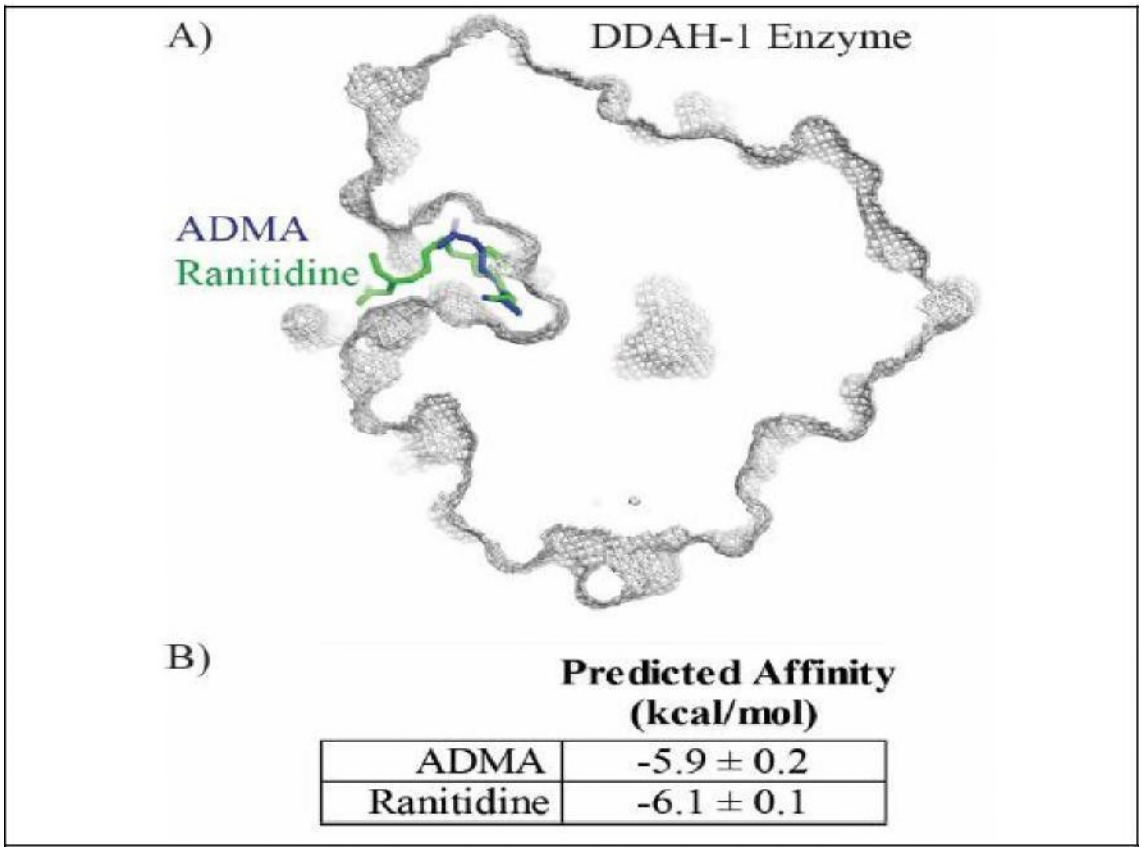
87. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH") which can occur in other tissues and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

88. 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]."[25]

89. 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. *See* Fig. 2.

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

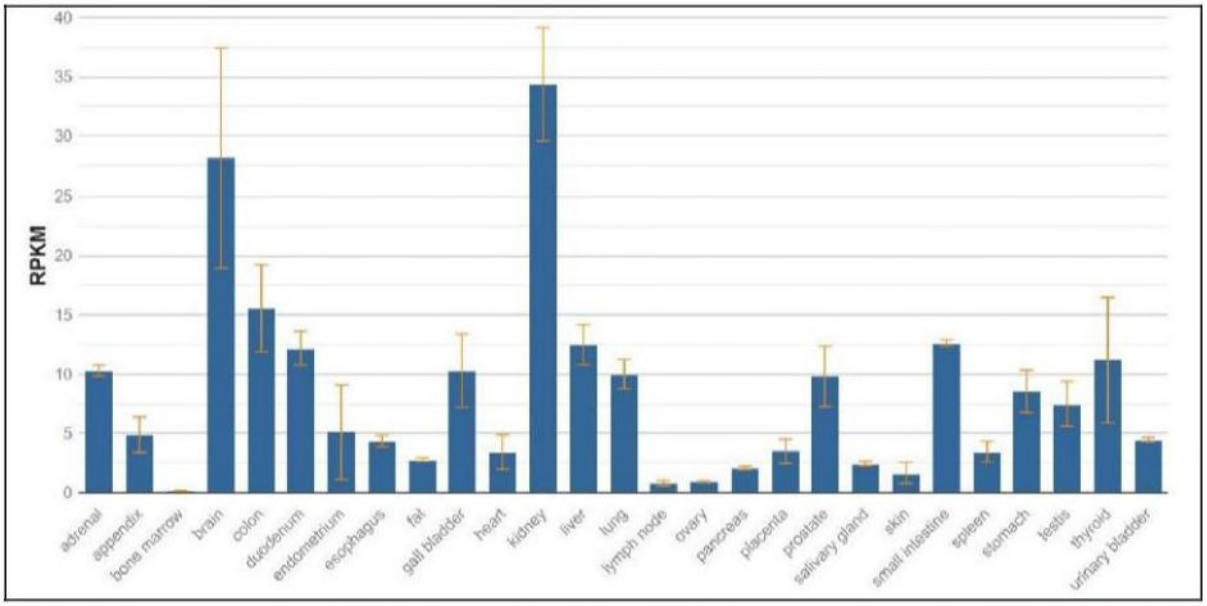
Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

90. 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. *See* Fig. 3, derived from the National Center for Biotechnology Information.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



91. DDAH-1 is 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 numerous organs, including the colon.

92. Likely due to the perceived high safety profile of ranitidine, very few epidemiological studies have been conducted on this drug. The human data, although limited at this point, is nevertheless even more concerning.

93. 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.[26] One of the variables investigated by the authors was the patients' consumption of a prescription antacid, including Zantac. The authors concluded that "[r]ecent use of ulcer treatment medication [such as

[26] 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).

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 noted 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.

94. In addition, 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.[27]

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

95. 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.

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

97. 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.

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

98. 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.

99. "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).

100. Defendants ignored these regulations, disregarding the scientific evidence available to them, and did not report to the FDA significant new information affecting the safety or labeling of Zantac.

101. 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.

102. In a 1981 study published by Glaxo, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[28] 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.

[28] 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).

103. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, Glaxo published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[29] 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, Glaxo also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk.

104. In fact, none of the Defendants ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with its trials associated with ranitidine. That is because mass spectrometry requires heating of up to 130 degrees Celsius, which can result in excessive amounts of nitrosamines being formed. Had the Defendants used a mass spectrometry assay, it would have revealed in the finding of large amounts of NDMA, and the FDA would never have approved Zantac as being safe.

105. 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).

[29] 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).

E. Plaintiff-Specific Allegations

106. Plaintiff purchased and used over-the-counter ("OTC") brand-name Zantac for over two decades. She took both the 75 mg and 150 mg doses, regularly and on an almost daily basis.

107. Approximately 24 years ago, Plaintiff was first advised that she needed to reduce her stomach acid when she had an endoscopy. Shortly thereafter, she began taking Zantac.

108. Plaintiff began taking OTC Zantac 75 mg as soon as it became available on the U.S. market. As soon as OTC Zantac 150 mg became available in the U.S., Plaintiff began taking that instead believing it would give longer lasting results.

109. Plaintiff took Zantac because, as advertised, Zantac provided quick relief for her acid reflux and "sour stomach" gastrointestinal symptoms as well as a preventative to prevent acid reflux in the future. Indeed, Plaintiff saw Zantac's advertisements featuring firemen arriving in a firetruck, illustrating Zantac's promise of fast relief.

110. Plaintiff also took Zantac because, as advertised, Zantac provided relief from sour stomach and other gastrointestinal symptoms caused by eating spicy foods, when taken either in combination with or at intervals close in time to such foods. Indeed, Plaintiff saw Zantac's advertisements featuring consumers eating tacos, pizza, and other foods that might cause indigestion with impunity because they had Zantac on hand.

111. Plaintiff thoroughly read Zantac's packaging directions and warning labels. The Zantac packaging promised instant relief, and also indicated that Zantac could be taken with foods causing stomach and other gastrointestinal symptoms. Nowhere were there any warnings that Zantac might cause cancer, that it should not be taken at times close to or with meals, or that Plaintiff should take any inhibitors to reduce the risk of cancer.

112. In April 2018, Plaintiff was diagnosed with stage IIIC colon cancer.

113. In order to treat her cancer, Plaintiff underwent surgery and had a large section of her colon removed. Plaintiff then had to undergo chemotherapy treatments that consisted of a three to four infusion of chemotherapy drugs, followed by the fitting of an infusion pump that administrated chemotherapy drugs over the next 72 hours. This process was repeated every two weeks over a six-month period.

114. In August 2018, Plaintiff stopped taking OTC Zantac.

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

116. Plaintiff's colon cancer was caused by ingestion of Zantac.

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

118. Plaintiff did not learn of the link between her cancer and Zantac exposure until November 2019, when she learned that antacid products containing ranitidine were being recalled.

119. Plaintiff's life has been irreparably altered by her diagnosis. Plaintiff was only 58 years old when she was diagnosed with cancer. She and her husband were just finishing the process of winding up an industrial hardware business that they owned so that they could semi-retire and pursue life-long dreams.

120. Plaintiff and her husband had considered, among other things, starting a smaller, more manageable business that would allow them more freedom to pursue recreational activities and spend time with family.

121. Plaintiff and her husband are avid sailors, and had always dreamed of completing the World ARC, a supported world circumnavigation, and doing other long-distance races in the Caribbean. Now, however, Plaintiff cannot be away from home or offshore on a sailboat for

extended periods of time because of fear that she may fall ill, and also because she requires regular medical follow up.

122. Plaintiff has no family history of cancer and was always conscious of her health. She ate well, never smoked, drank in moderation, and always exercised. All of these efforts, however, have been in vain, for taking Defendants' Zantac has undone it all.

123. Plaintiff now lives under the cloud of cancer. Plaintiff knows of many people who, even after having been cancer free for years, have had their cancers return. Plaintiff's daughter recently married, and Plaintiff wonders if she will be there to meet her grandchildren. Indeed, whenever Plaintiff considers any future plans, she always qualifies it with "If I am here."

F. Exemplary / Punitive Damages Allegations

124. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. 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 label, marketing, and promotion to mislead consumers.

125. This was not done by accident or through some justifiable negligence. Rather, Defendants knew that it 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' accomplished this not only through its misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiff was denied the right to make an informed decision about whether to purchase and use

Zantac, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

126. Defendants' conduct alleged herein was done with intentional, wanton and malicious disregard for the plaintiff's rights. Accordingly, Plaintiff requests punitive damages against Defendants for the harms caused to Plaintiff.

G. Tolling of the Statute of Limitations and Estoppel

127. Within the time period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable diligence that exposure to Zantac is injurious to human health.

128. Plaintiff did not discover and did not know of facts that would cause a reasonable person to suspect the risk associated with the use of Zantac, nor would a reasonable and diligent investigation by Plaintiff have disclosed that Zantac would cause Plaintiff's illnesses.

129. Through affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with use of Zantac. Instead of disclosing to consumers the link between Zantac and the carcinogen NDMA, Defendants misled the public into believing Zantac was safe by repeatedly touting its safety, and affirmatively representing that longstanding science supported the safety of Zantac.

130. Defendants had a duty to disclose the true character, quality and nature of Zantac because this was non-public information over which Defendants continue to have control. Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or health facilities, yet Defendants failed to disclose the information to the public, including Plaintiff.

131. Defendants had the ability to and did spend enormous amounts of money in furtherance of marketing and promoting a profitable product, notwithstanding the known or reasonably knowable risks. Plaintiff and medical professionals could not have afforded to and could not have possibly conducted studies to determine the nature, extent, and identity of related health risks and were forced to rely on Defendants' representations.

132. Defendants knowingly, affirmatively, and actively concealed the true risks of NDMA exposure associated with Zantac and never disclosed those risks to Plaintiff.

133. As a result of Defendants' actions, Plaintiff could not reasonably have known or learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions until Valisure filed its Citizen Petition disclosing the extremely high levels of NDMA produced by Zantac.

134. The expiration of any applicable statute of limitations has been equitably tolled by reason of Defendants' misrepresentations and concealment, and Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Zantac.

COUNT I – STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

135. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

136. At all relevant times, Defendants engaged in the business of developing, designing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and selling Zantac products.

137. Defendants developed, designed, tested, manufactured, packaged, labeled, marketed, promoted, distributed, and sold the Zantac products used by Plaintiff, as described herein.

138. Zantac is defective in design and/or formulation because it is unreasonably dangerous for its intended purpose. The chemical structure of ranitidine itself is inherently unstable and contains the two chemical components for the formation of NDMA, a potent carcinogen. When ingested, Zantac forms extremely high levels of NDMA in the body. NDMA is a human carcinogen associated with various types of cancers, including colon cancer.

139. Zantac's design defect existed at the time the product left the Defendants' possession and reached Plaintiff without substantial change affecting that defective condition.

140. Zantac is defective in design because the product fails to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable by Defendants in that, when ingested, Zantac forms extremely high levels of NDMA in the body.

141. At all relevant times, the foreseeable dangers and risks of Zantac's design defect exceeded the products' alleged benefits.

142. Zantac products were and are more dangerous than alternative products. Indeed, at the time Defendants designed Zantac products, the state of the industry's scientific knowledge and existing technology were such that less risky design formulations were attainable.

143. At the time Zantac products left Defendants' control, there were practical, technically feasible, and safer alternative design formulations that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Zantac products.

144. At the time Zantac left Defendants' hands, an average consumer could not have reasonably anticipated the dangerous nature of Zantac nor fully appreciate the attendant risk of injury associated with its use, including the risk of developing cancer.

145. At all relevant times, the Defendants knew that ordinary patients would use Zantac without knowledge of the dangers involved with such use, and knowingly designed Zantac with the defect in order to maximize profits.

146. Had Plaintiff known of the defect in Zantac, she would not have taken it. Instead, she would have taken safer alternatives that would not have exposed her to NDMA.

147. As a direct and proximate result of ingesting Zantac, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT II – STRICT LIABILITY (FAILURE TO WARN)

148. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

149. At all relevant times, Defendants engaged in the business of developing, designing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and selling Zantac products.

150. Defendants developed, designed, tested, manufactured, packaged, labeled, marketed, promoted, distributed, and sold the Zantac products used by Plaintiff, as described herein.

151. At all relevant times, Zantac posed a substantial danger to patients' bodies because NDMA, a potent carcinogen, forms in high quantities in the human body as a result of Zantac ingestion.

152. The Defendants were aware of the risks that Zantac posed to those who ingested it, and the risks Zantac posed to those who used it were knowable at the time the Defendants manufactured, sold, or distributed Zantac. Indeed, at the time the Defendants manufactured and sold Zantac, the scientific community had already identified the dangers of NDMA formation in ranitidine.

153. The risk that NDMA would form in the human body as a result of Zantac ingestion, and the associated development of Plaintiff's cancer, were known or knowable in light of the scientific and medical knowledge available at the time of manufacture and distribution of Zantac. At all times since Zantac was commercially sold in the U.S., the Defendants knew that ranitidine would form into NDMA in the body, and that NDMA was a carcinogen

154. At the time Zantac left Defendants' hands, an average consumer could not have reasonably anticipated the dangerous nature of Zantac nor fully appreciate the attendant risk of injury associated with its use, including the risk of developing cancer.

155. At all relevant times, the Defendants knew that ordinary patients would use Zantac without knowledge of the dangers involved with such use.

156. Defendants could have reduced or avoided the foreseeable risks of harm from Zantac products by providing reasonable warnings or instructions.

157. Defendants failed to warn Plaintiff about the dangers of Zantac.

158. Defendants failed to warn the FDA about the dangers of Zantac.

159. Defendants knew or should have known that the minimal warnings disseminated with their Zantac products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

160. Plaintiff used Defendants' Zantac products for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics

161. Had Defendants adequately warned and instructed Plaintiff about the dangers of Zantac, she would not have taken it. Instead, she would have taken safer alternatives that would not have exposed her to NDMA.

162. As a direct and proximate result of ingesting Zantac, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT III - NEGLIGENCE

163. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

164. At all relevant times, Defendants had a duty to exercise reasonable care in the development, design, testing, manufacture, packaging, labeling, marketing, promotion, distribution, and sale Zantac products used by Plaintiff, as described herein.

165. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Zantac and

appropriate, complete, and accurate warnings concerning the potential adverse effects of Zantac and, in particular, its ability to transform into the carcinogenic compound NDMA.

166. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Zantac and, specifically, the carcinogenic properties of NDMA when Zantac is ingested.

167. Accordingly, Defendants knew or, in the exercise of reasonable care, should have known that use of Zantac products could create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

168. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Zantac were unaware of the risks and the magnitude of the risks associated with use of Zantac.

169. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Rather, Defendants deliberately refused to test Zantac products because they knew that the chemical posed serious health risks to humans, and intentionally concealed information and further made false and/or misleading statements concerning the safety and use of Zantac.

170. Defendants breached their duty of care by, among other things:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Zantac products without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Zantac while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and

studies of Zantac and the carcinogenic potential of NDMA as created in the human body as a result of ingesting Zantac, and, consequently, the risk of serious harm associated with human use of Zantac;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Zantac products were safe for their intended consumer use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Zantac products so as to avoid the risk of serious harm associated with the prevalent use of Zantac products;

e. Failing to design and manufacture Zantac products so as to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use Zantac products;

g. Failing to disclose to Plaintiff, users/consumers, and the general public that use of Zantac presented severe risks of cancer and other grave illnesses;

h. Failing to warn Plaintiff, consumers, and the general public that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Zantac products;

j. Representing that their Zantac products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose;

k. Declining to make or propose any changes to Zantac products' labeling or other promotional materials that would alert consumers and the general public of the risks of Zantac;

l. Advertising, marketing, and recommending the use of the Zantac products, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to Zantac;

m. Continuing to disseminate information to its consumers, which indicate or imply that Defendants' Zantac products are not unsafe for regular consumer use; and

n. Continuing the manufacture and sale of their products with the knowledge that the products were unreasonably unsafe and dangerous.

171. Defendants' conduct constitutes negligence, gross negligence and willful misconduct.

172. Defendants knew that Zantac formed NDMA in the human body following ingestion, and by intentionally withholding a safer design of Zantac, while failing to warn (let alone adequately warn) of the known risks of Zantac, the Defendants acted in reckless disregard of, or with a lack of substantial concern for, the rights of others.

173. The Defendants intentionally designed Zantac products in the way that they did and withheld the safer designs from patients while in disregard of the known risk of NDMA formation from Zantac usage, making it highly probable that harm would result.

174. The Defendants knew that their conduct would harm Plaintiff, but chose to withhold any warning to Plaintiff, or to utilize a safer design for Zantac, simply to make more money for themselves.

175. As a direct and proximate result of Defendants' negligence, gross negligence and willful misconduct, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT IV – BREACH OF EXPRESS WARRANTY

176. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

177. At all relevant times, Defendants are or were manufacturers and sellers of Zantac, and Plaintiff was a buyer.

178. Defendants, by and through statements made in labels, publications, package inserts, and other written materials intended for consumers and the general public, expressly represented that Zantac products were safe to human health and the environment, effective, fit, and proper for their intended use.

179. Defendants 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.

180. 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.

181. Defendants' representations 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.

182. Defendants' Zantac products did not conform to Defendants' representations regarding their safety, efficacy, and fitness for their intended use.

183. Defendants breached their express warranties because, among other things, Zantac products were defective, dangerous, and unfit for use.

184. 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.

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

186. Defendants had sole access to material facts concerning the nature of the risks associated with their 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.

187. As a direct and proximate result of Defendants' breach of their express warranties, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT V – BREACH OF IMPLIED WARRANTIES

188. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

189. At all relevant times, Defendants are or were manufacturers and sellers of Zantac.

190. Implied warranties run from each Defendant to consumers like Plaintiff. As such, Defendants impliedly warranted that the Zantac they sold were reasonably fit for either the uses intended or the uses reasonably foreseeable by the Defendants, and fit and safe for the particular purpose for which Defendants knowingly sold them.

191. Defendants are in the business of developing, designing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and selling Zantac products for the prevention of acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.

192. Plaintiff relied on the Defendants' skill or judgment to provide a product suitable for this purpose.

193. Defendants had reason to know that Plaintiff would rely on the Defendants' skill or judgment.

194. Zantac products are not reasonably fit for either the uses intended or the uses reasonably foreseeable by the Defendants, nor are they fit for the particular purpose for which Defendants knowingly sold them.

195. Defendants breached their implied warranties because, among other things, Zantac products are toxic to patients when put to either the uses intended or the uses reasonably foreseeable by Defendants, or when used for the particular purpose for which Defendants knowingly sold it.

196. The dangers of Zantac to Plaintiff were known and knowable to the Defendants at the time of manufacture and sale. Yet the Defendants marketed Zantac without adequate warnings about the risks that Zantac would produce NDMA in the body when ingested, and instead made representations about its safety, efficacy, and fitness for their intended use, to which they did not conform.

197. As a direct and proximate result of Defendants' breach of their implied warranties, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT VI – NEGLIGENT MISREPRENTATION

198. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

199. Defendants represented to Plaintiff, the healthcare industry, and the public that Zantac was safe for its intended use, and/or omitted material facts about Zantac's dangers. Defendants represented that Zantac products were safe in general, that they were safe for use by individuals such as Plaintiff, and that they were safe as a consumer medication, and/or omitted material facts regarding Zantac's production of high levels of the carcinogen NDMA.

200. Defendants continuously and repeatedly represented that Zantac was safe for its intended use on its packaging and labeling, and/or omitted material facts about Zantac's dangers. When Plaintiff purchased Zantac products, she thoroughly read the product's packaging and labeling, which represented that Zantac was safe for heartburn, acid indigestion, sour stomach, gastroesophageal reflux, and other gastrointestinal conditions, and/or omitted material facts about Zantac's dangers.

201. Defendants continuously and repeatedly represented that Zantac was safe for its intended use and/or omitted material facts about Zantac's dangers through their aggressive media campaigns, which touted Zantac's safety. This media campaign included, among other things, print advertisements, television commercials, and internet advertising. Defendants' advertisements specifically represented that Zantac was safe for use in combination with nitrate-containing foods, such as tacos and pizza. Plaintiff saw Defendants' advertisements touting Zantac's safety and/or omitting material facts about Zantac's dangers throughout the time she was using Zantac.

202. Defendants knew or should have known that their representations about Zantac's safety were false and/or made representations about Zantac's safety without knowledge or their truth or falsity, and/or knew of should have known that they were omitting material facts about Zantac's dangers. Even at the time ranitidine was developed, there was already scientific literature suggesting that drugs like ranitidine are highly likely to form NDMA when combined with other substances found in the body. Furthermore, 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.

203. Defendants intended for their representations about Zantac's safety and/or their omissions of material facts about Zantac's dangers to induce Plaintiff and consumers to purchase

and use Zantac and to continue to use Zantac on a regular basis, including in combination with nitrate-containing foods. Indeed, through Defendants' aggressive marketing campaigns, which touted Zantac's safety and/or omitted material facts about Zantac's dangers, Zantac became one of the best-selling drugs in history.

204. Plaintiff justifiably relied to her detriment on Defendants' representations regarding Zantac's safety and/or Defendants' omissions of material facts about Zantac's dangers. Plaintiff justifiably expected that a drug available on the U.S. market would be adequately tested and that any and all risks would be disclosed. Plaintiff would have never taken Zantac had she known of the risks, and did in fact purchase and use Zantac in justifiable reliance on Defendants' representations that Zantac was safe and/or Defendants' omissions of material fact about Zantac's dangers.

205. As a direct and proximate result of Defendants' negligent and/or grossly negligent misrepresentations that Zantac was safe and/or Defendants' negligent and/or grossly negligent omissions of material facts about Zantac's dangers, Plaintiff and developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT VII – FRAUDULENT MISREPRENTATION

206. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

207. Defendants represented to Plaintiff, the healthcare industry, and the public that Zantac was safe for its intended use, and/or omitted material facts about Zantac's dangers.

Defendants represented that Zantac products were safe in general, that they were safe for use by individuals such as Plaintiff, and that they were safe as a consumer medication, and/or omitted material facts regarding Zantac's production of high levels of the carcinogen NDMA.

208. Defendants continuously and repeatedly represented that Zantac was safe for its intended use on its packaging and labeling, and/or omitted material facts about Zantac's dangers. When Plaintiff purchased Zantac products, she thoroughly read the product's packaging and labeling, which represented that Zantac was safe for heartburn, acid indigestion, sour stomach, gastroesophageal reflux, and other gastrointestinal conditions, and omitted material facts about Zantac's dangers.

209. Defendants continuously and repeatedly represented that Zantac was safe for its intended use and/or omitted material facts about Zantac's dangers through their aggressive media campaigns, which touted Zantac's safety. This included, among other things, print advertisements, television commercials, and internet advertising. Defendants' advertisements specifically represented that Zantac was safe for use in combination with nitrate-containing foods, such as tacos and pizza. Plaintiff saw Defendants' advertisements touting Zantac's safety and/or omitting material facts about Zantac's dangers throughout the time she was using Zantac.

210. Defendants knew that their representations about Zantac's safety were false and knew that they were omitting material facts about Zantac's dangers. 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 were aware of articles published in peer-reviewed scientific journals detailing the results of experiments showing that ranitidine exposed to gastric fluid in combination with nitrites produced toxic and mutagenic effects, as well as countless other studies documenting ranitidine's propensity to form NDMA and

the links between NDMA and cancer. In an intentional attempt to discredit those sources, Defendants caused bogus experiments to be conducted, concluding that ranitidine was safe for the purposes for which Defendants were marketing it, and caused the results of those experiments to be published. Defendants knew that those experiments, which had been conducted at Defendants' behest, were intentionally rigged to yield results that would support Defendants' knowingly false representations that Zantac was safe.

211. Defendants intended for their representations about Zantac's safety and/or their omissions of material facts about Zantac's dangers to induce Plaintiff and consumers to purchase and use Zantac and to continue to use Zantac on a regular basis, including in combination with nitrate-containing foods. Indeed, through Defendants' aggressive marketing campaigns, which touted Zantac's safety, Zantac became one of the best-selling drugs in history.

212. Plaintiff relied to her detriment on Defendants' representations regarding Zantac's safety and/or Defendants' omissions of material facts about Zantac's dangers. Plaintiff expected that a drug available on the U.S. market would be adequately tested and that any and all risks would be disclosed. Plaintiff would have never taken Zantac had she known of the risks, and did in fact purchase and use Zantac in reliance on Defendants' representations that Zantac was safe and/or on Defendants' omissions of material facts about Zantac's dangers.

213. As a direct and proximate result of Defendants' intentional and/or fraudulent misrepresentations that Zantac was safe and/or Defendants' intentional and/or fraudulent omissions of material facts about Zantac's dangers, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future

earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

COUNT VIII – FRAUDULENT CONCEALMENT

214. Plaintiff incorporates by reference each allegation set forth in paragraphs 1-134 as if fully stated herein.

215. Defendants concealed from and/or failed to disclose to Plaintiff, the healthcare industry, and the public material facts about Zantac's dangers, including, among other things, that: ingesting Zantac led to the production of high levels of the NDMA in the human body; NDMA was associated with an increased risk of cancer; Zantac exposed to gastric fluid in combination with nitrites produced toxic and mutagenic effects; patients taking Zantac should eat a diet low in nitrates and nitrites; Zantac should not be taken at times close to or with meals; and, patients taking Zantac should take nitrosation inhibitors, such as ascorbic acid.

216. Defendants knew or should have known that these and other material facts about Zantac's dangers should have been disclosed and/or not concealed.

217. Defendants had a duty to speak because they: had a duty to monitor the results of scientific experiments testing for the adverse effects associated with ranitidine products; had special knowledge about Zantac's dangers to which Plaintiff, the healthcare industry, and the public did not have access; and were in possession of information about Zantac's dangers that was not readily available to Plaintiff, the healthcare industry, or the public.

218. Defendants knew that by concealing and/or failing to disclose information about the Zantac's dangers patients like Plaintiff would be induced to purchase and ingest Zantac with no knowledge of its dangers, and without taking any safety precautions. Defendants knew that this information was not readily available to Plaintiff, the healthcare industry, or the public, and

Plaintiff, the healthcare industry, and the public did not have an equal opportunity or practicable way to discover the truth about Zantac's dangers. Indeed, through Defendants' concealment of and/or failure to disclose Zantac's dangers, Zantac became one of the best-selling drugs in history.

219. Plaintiff relied to her detriment on Defendants' concealment of and/or failure to disclose Zantac's dangers and/or recommended safety precautions. Plaintiff expected that a drug available on the U.S. market would be adequately tested and that any and all risks and/or safety precautions would be disclosed. Plaintiff would have never taken Zantac had she known of the risks, and did in fact purchase and use Zantac in reliance on Defendants' concealment of and/or failure to disclose Zantac's dangers and/or recommended safety precautions.

220. As a direct and proximate result of Defendants' intentional and/or fraudulent concealment of and/or failure to disclose Zantac's dangers and/or recommended safety precautions, Plaintiff developed cancer and suffered bodily injury resulting in pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, medical care and treatment, loss of earnings, and the loss of the ability for future earnings. These losses are permanent and continuing in nature, and Plaintiff will suffer these losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter an order or judgment against Defendants, including the following:

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 from future wrongful practices;

C. Pre-Judgement and post-judgment interest as provided by law;

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

E. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable.

DATED: 06/02/2020

Respectfully submitted,

BUCKNER + MILES

By */s/ Brett E. von Borke*

David M. Buckner, Esq., FBN 60550
Brett E. von Borke, Esq., FBN 0044802
3350 Mary Street
Coconut Grove, Florida 33133
Telephone: 305.964.8003
E-mail: david@bucknermiles.com
E-mail: vonborke@bucknermiles.com

Counsel for Plaintiff and the Proposed Classes