Jennifer A. Moore, Esq. (SBN: 206779)
jennifer@moorelawgroup.com
MOORE LAW GROUP, PLLC
1473 South 4th Street
Louisville, KY 40208
Tel: (502) 717-4080
Fax: (502) 717-4086

Douglas A. Dellaccio (AL Bar No.: asb-4578-l75d)
(Pro Hac Vice forthcoming)
Lauren S. Miller (AL Bar No.: asb-6193-v74n)
(Pro Hac Vice forthcoming)
CORY WATSON, P.C.
2131 Magnolia Avenue S.
Birmingham, AL 35205
Tel: (205) 328-2200
Fax: (205) 852-6299
ddellaccio@corywatson.com
lmiller@corywatson.com

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GARY HART,

Plaintiff,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.;

SANOFI US SERVICES INC.;

PFIZER, INC.; and

GLAXOSMITHKLINE, LLC,

Defendants.

Case No. '19CV2296 W MDD

COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

INTRODUCTION

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

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

3. These recent revelations by independent researchers have caused widespread recalls of Zantac both domestically and internationally, and the FDA is actively investigating the issue, with its 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.

4. 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.

5. Plaintiff Gary Hart took Zantac for approximately eight (8) years and, as a result, developed cancer. His cancer was caused by NDMA exposure created by the ingestion of Zantac. This lawsuit seeks damages against the Defendants for causing Mr. Hart to develop colon cancer.

PARTIES

6. Plaintiff Gary Hart (hereinafter "Plaintiff"), resides in San Diego County, California and is citizen of California and not of any other state.

7. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") is a Delaware corporation with its principal place of business located at 900 Ridgebury

Road, Ridgefield, Connecticut 06877. BI is a citizen of Connecticut and Delaware, and not of any other state. BI is a subsidiary of the German company Boehringer Ingelheim Corporation. BI owned and controlled the NDA for over-the-counter ("OTC") Zantac between December 2006 and January 2017, and manufactured and distributed the drug in the United States, including California, during that period. Under California law, BI was a brand-name manufacturer of Zantac and, through its negligence and willful misconduct, caused the labeling on the Zantac label to not include any warning for cancer.

8. Defendant Sanofi US Services Inc., ("Sanofi") is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of Sanofi S.A. Sanofi is a citizen of Delaware and New Jersey and is not a citizen of any other state. Sanofi controlled the NDA for OTC Zantac starting in January 2017 through the present and manufactured and distributed the drug in the United States, including California, during that period. Sanofi voluntarily recalled all brand name OTC Zantac on October 18, 2019. Under California law, Sanofi is a brand-name manufacturer of Zantac and, through its negligence and willful misconduct, caused the labeling on the Zantac label to not include any warning for cancer.

9. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer is a citizen of Delaware and New York and is not a citizen of any other state. In 1993, Glaxo Wellcome, plc formed a joint venture with Warner-Lambert, Inc. to develop and obtain OTC approval for Zantac. 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 Wellcome 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. Under California

law, Pfizer was a brand-name manufacturer of Zantac and, through its negligence and willful misconduct, caused the labeling on the Zantac label to not include any warning for cancer.

10. Defendant GlaxoSmithKline, LLC ("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 Zantac label to not include any warning for cancer.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of $75,000, exclusive of interest and costs.

12. This Court has personal jurisdiction over each Defendant insofar as each Defendant is authorized and licensed to conduct business in the State of California, 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.

13. Additionally, the Defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this 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. The Plaintiff was, indeed, exposed to Zantac in this judicial district.

14. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to this claim occurred within this judicial district.

FACTUAL ALLEGATIONS

I. Brief History of Zantac and Ranitidine

15. Zantac was developed by John Bradshaw 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 by Glaxo in response to the then leading H2 blocker, cimetidine (Tagamet).

16. At the time that ranitidine was developed, there was scientific literature suggesting that drugs like ranitidine, which contain a dimethylamine ("DMA") group within the molecule, are highly likely to form NDMA, when combined with other substances, *i.e.*, nitrite, already found in the body. Indeed, nitrite is not only naturally found in the body, but bacteria and enzymes in the body, reduce the nitrates (NO3) found in food into nitrites (NO2-) and many foods and preservatives contain nitrates. Glaxo scientists should have known that human physiology and diet would lead to the development of NDMA in the human body after ingestion of ranitidine.

17. Due in large part to GSK's marketing strategy, Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986. 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] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

18. 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.

19. On September 13, 2019, in response to a citizen's petition filed by Valisure, Inc. (discussed in detail below), U.S. and European regulators stated that they are 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 indicated unacceptable levels of NDMA so far.

---

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

23. On November 1, 2019, the FDA released is preliminary results, showing unsafe levels of NDMA in various ranitidine products, including the brand name products controlled by Sanofi.

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.

II. 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. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[2] 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.

26. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human

---

[2] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, THE GLOBE AND MAIL CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA adducts in humans after exposure to methylating agents*, 405 MUTAT. RESEAR. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

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. 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.

28. 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. 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 μg (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. 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.

29. Tobacco smoke also contains NDMA. One filtered cigarette contains between 5 to 43 ng of NDMA.

30. In mouse studies examining the carcinogenicity of NDMA 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.

31. 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.

32. 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.

33. 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).

34. Research shows that lower levels of NDMA, *i.e.*, 40 ng, are fully metabolized in the liver, but high doses enter the body's general circulation.

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

36. 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.

37. Pursuant to the EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[3]

38. 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) v. 304,500 ng/day (Zantac).

39. In a 1995 epidemiological case-control study looking at NDMA dietary

---

[3] *See* https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

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.[4]

40. 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.[5]

41. 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.[6]

42. 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.[7]

43. 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.[8]

44. 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

---

[4] 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).

[5] La Vecchia, *et al*., *Nitrosamine intake and gastric cancer risk*, 4 EUROP. J. CANCER. PREV. 469–474 (1995).

[6] 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).

[7] 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)

[8] 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).

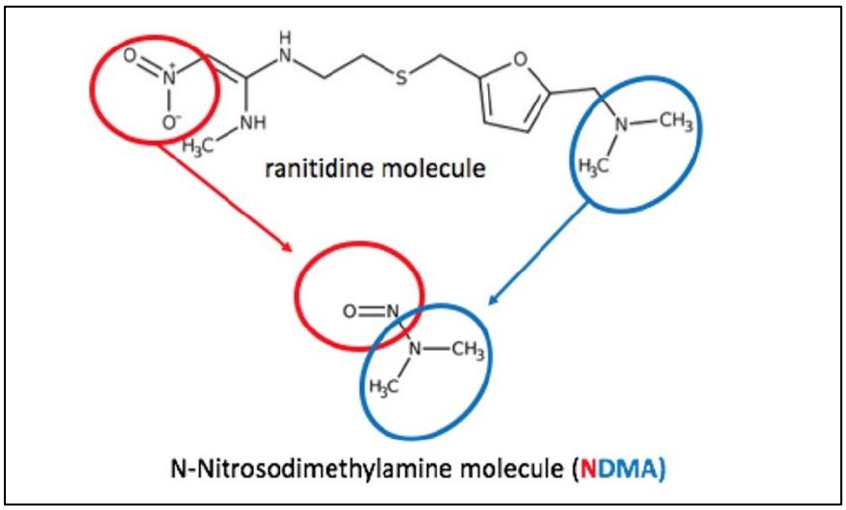
"[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[9]

45. 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.[10]

III. How Ranitidine Transforms into NDMA Within the Body

46. 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 DMA group which are well known to combine to form NDMA. *See* Fig. 1. Thus, ranitidine produces NDMA by "react[ing] with itself," which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.

Figure 1 – Ranitidine Structure & Formation of NDMA



[9] 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).

[10] 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).

47. 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.[11] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[12]

48. In 1981, the very year Zantac was launched commercially outside of the US, two exchanges in The Lancet—one of the most widely read and respected medical and scientific publications—discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H2 blocker, has a similar chemical structure to ranitidine.

49. 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. When ranitidine was exposed to gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects[.]"[13] Dr. de Flora hypothesized that these effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our 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 ascorbid acid.

---

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

[13] De Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, THE LANCET 993-994 (Oct. 31, 1981).

50. GSK responded to Dr. de Flora's concern.[14] A group of GSK researchers specifically noted they "were obviously concerned as to whether or not a mutagenic N-nitroso derivative of ranitidine could be formed in the stomach." Apparently, GSK was fully aware of the potential NDMA issue. GSK acknowledged that ranitidine that in the presence of nitrites, a "N-nitroso nitrolic acid derivative was formed" that was "mutagenic[.]" GSK, however, dismissed this finding because the levels of nitrate used were much higher than what would be expected to occur after a meal and, therefore, any N-Nitroso compound found would not likely occur in human in real world experiences. GSK asserted that "no mutagenic nitrosated product of ranitidine is likely to be formed in man under any conceivable physiological conditions[.]"

51. 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 effects (ability to harm DNA).[15] The researchers concluded:

> [I]t 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[.]

52. Then, again in 1983, Dr. de Flora, along with four other researchers, published the complete findings.[16] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine[.]" *Id.* Again, the authors noted that:

> [T]he widespread clinical use [of ranitidine] and the possibility of a long-term

---

[14] Brittain, *et al*., *The Safety of Ranitidine*, THE LANCET 1119 (Nov. 14, 1981).
[15] Maura, *et al*., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LTTRS. 97-102 (1983).
[16] De Flora, *et al*., *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).

> 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.

Id.

53. 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.[17] 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.

54. 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.

55. 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

[17] Le Roux, *et al*., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012).

standard assays to test every batch of every medication it dispenses.

56. 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.[18] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

57. 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

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

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.

58. 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. This method was validated to a lower limit of detection of 100 ng.

59. Valisure 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.

60. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, *etc*.[19]

61. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

[19] *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.

Table 2 – Valisure Biologically relevant tests for NDMA formation		
Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

62. 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. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 ng level (over 7,000 for the 50 µg level).

63. 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.

64. 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.

65. 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 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.

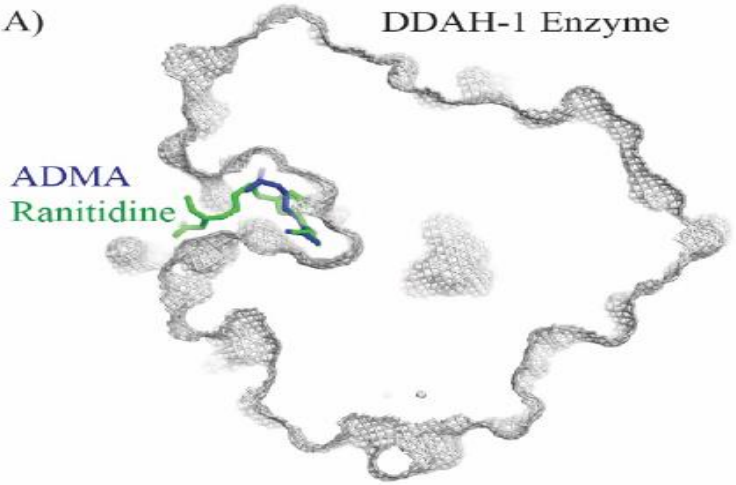
66. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues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

67. 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 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]."[20]

68. In Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

[20] 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).

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

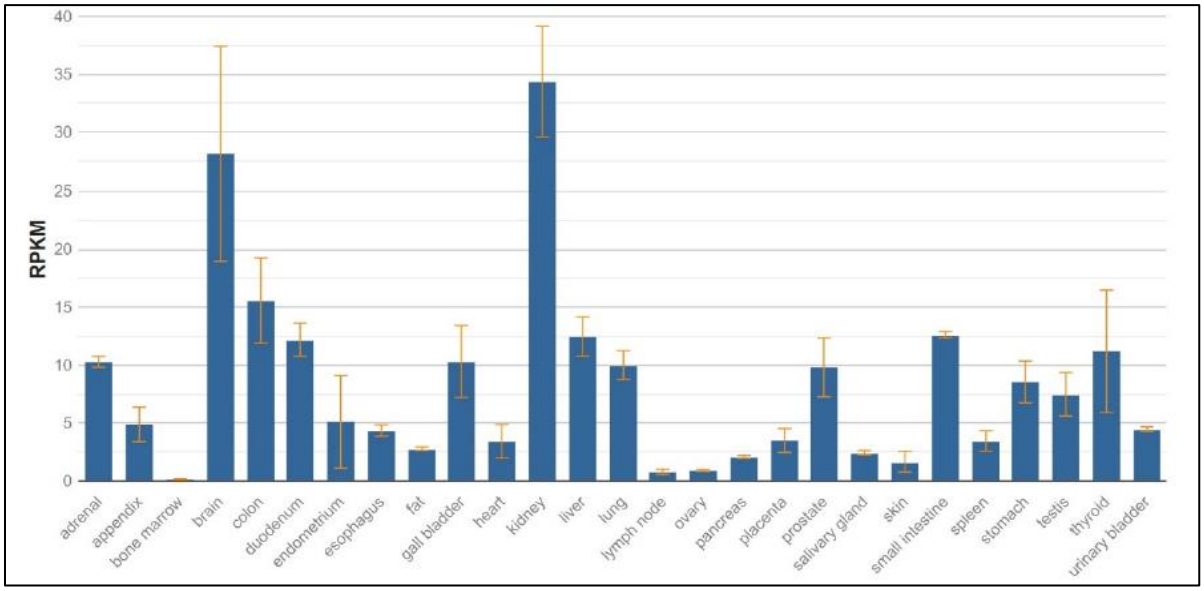


	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

69. 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.

70. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

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



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

72. In addition to the aforementioned *in vitro* studies that suggest a strong connection between ranitidine and NDMA formation, *in vivo* clinical studies in living animals add further weight to concern over this action and overall potential carcinogenicity. A study published in the journal *Carcinogenesis* in 1983 titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite. The authors of this study 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."[21]

73. 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.[22]

74. Likely due to the perceived high safety profile of ranitidine, very few epidemiological studies have been conducted on this drug.

75. 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.[23] 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.

76. 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

---

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

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

[23] 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).

administered with nitrite resulted in a significant DNA fragmentation.[24]

77. 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[.][25]

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

78. 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.

79. 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.

80. 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.

81. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information

---

[24] Brambilla, *et al.*, *Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance*, 52 CHEMICAL CARCINOGENESIS (1982).

[25] Valisure Citizen Petition, *see* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf

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.

82. Furthermore:

> 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).

83. 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.

84. 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.

85. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[26] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiff believe this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product.

[26] 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).

86. Indeed, in that same year, Dr. de Flora published a note in the Lancet discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found in food and in the body. The Defendants were aware of this as GSK specifically responded to the note and attempted to discredit it. Notwithstanding this legal risk signal, GSK did not test for this alarming cancer risk, and it did so intentionally.

87. 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.[27] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk.

88. In fact, on information and belief, none of the Defendants never used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with their trials associated with the ranitidine NDA. That is because when using mass spectrometry, it requires heating of up to 130 degrees

[27] 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).

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.

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

V. Plaintiff-Specific Allegations

90. Plaintiff began using generic prescription Zantac (ranitidine) in 2000 and continued to use it through 2008. He took 300 mg every day.

91. In May 2008, Plaintiff was diagnosed with colon cancer.

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

93. Plaintiff's cancer was caused by ingestion of ranitidine.

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

95. Plaintiff did not learn of the link between cancer and Zantac and/or ranitidine exposure until approximately November 2019.

VI. Exemplary / Punitive Damages Allegations

96. 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.

97. 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'

object was accomplished not only through their 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.

98. Accordingly, Plaintiff requests punitive damages against Defendants for the harms caused to Plaintiff.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY – DESIGN DEFECT

99. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

100. Plaintiff brings this strict liability claim against Defendants for defective design.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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.

106. 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.

107. 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 their 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 their Zantac products; and

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

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

109. 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.

110. 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.

111. 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.

112. 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.[28]

113. 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.

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

115. The 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.

116. Defendants' conduct, as described above, was reckless. Defendants risked

---

[28] *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).

the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Zantac products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

117. As a direct and proximate result of Defendants placing their 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.

118. As a proximate result of Defendants placing their 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.

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

120. 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

121. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

122. Plaintiff brings this strict liability claim against Defendants for failure to warn.

123. 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, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Zantac and NDMA. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Zantac and other ranitidine formulations within this judicial district and aimed at a consumer market. Defendants were at all relevant times involved in the retail and promotion of Zantac products marketed and sold in in this judicial district.

124. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Zantac products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Zantac products.

125. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Zantac products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Zantac. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

126. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Zantac products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

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

128. Even though Defendants knew or should have known that Zantac posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting Zantac, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff.

129. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers, *i.e.*, the reasonably foreseeable users, of the risks of exposure to their products. Defendants have wrongfully concealed information concerning the dangerous nature of Zantac and the potential for ingested Zantac to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of Zantac products.

130. 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.

131. Plaintiff was exposed to Defendants' Zantac products without knowledge of their dangerous characteristics.

132. At all relevant times, Plaintiff used and/or was exposed to the use of Defendants' Zantac products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

133. Plaintiff could not have reasonably discovered the defects and risks associated with Zantac products prior to or at the time of Plaintiff consuming Zantac. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendants to

know about and disclose serious health risks associated with using Defendants' products.

134. 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.

135. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Zantac; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Zantac.

136. This alleged failure to warn is not limited to the information contained on Zantac's labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Zantac through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

137. Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of their products and the risks associated with the use of Zantac.

138. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Zantac products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication.

139. As a direct and proximate result of Defendants placing defective Zantac products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

140. As a proximate result of Defendants placing defective Zantac products into the stream of commerce, 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.

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

142. 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 III: NEGLIGENCE

143. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

144. Defendants, directly or indirectly, caused Zantac products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Zantac within this judicial district and aimed at a consumer market within this district.

145. At all relevant times, Defendants had a duty to exercise reasonable care in

the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Zantac products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

146. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Zantac products. 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.

147. 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.

148. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of Zantac products could cause or be associated with Plaintiff's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

149. 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.

150. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Zantac products, in that Defendants manufactured and produced defective Zantac which carries the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of

these risks and injuries. Indeed, Defendants deliberately refused to test Zantac products because they knew that the chemical posed serious health risks to humans.

151. Defendants were negligent in their promotion of Zantac, outside of the labeling context, by failing to disclose material risk information as part of their promotion and marketing of Zantac, including the internet, television, print advertisements, *etc*. Nothing prevented Defendants from being honest in their promotional activities, and, in fact, Defendants had a duty to disclose the truth about the risks associated with Zantac in their promotional efforts, outside of the context of labeling.

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

153. Defendants' negligence included:

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 their 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.

154. Defendants knew and/or should have known that it was foreseeable consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Zantac.

155. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Zantac.

156. Defendants' negligence was the proximate cause of Plaintiff's injuries, *i.e.*, absent Defendants' negligence, Plaintiff would not have developed cancer.

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

158. As a direct and proximate result of Defendants placing defective Zantac products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

159. As a proximate result of Defendants placing defective Zantac products into the stream of commerce, 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.

160. As a proximate result of Defendants placing defective Zantac products

into the stream of commerce, as alleged herein, Plaintiff sustained a loss of income, and loss of earning capacity.

161. 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 IV: BREACH OF EXPRESS WARRANTIES

162. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

163. 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.

164. 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 their 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.

165. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with Zantac is not limited to representations made on the labeling.

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

the purchasers of their 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.

167. 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.

168. 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.

169. 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.

170. 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 their 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 their 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.

171. 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.

172. 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.

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

174. 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.

175. 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.

176. 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.

177. 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.

178. 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.

179. 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

180. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

181. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Zantac products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce.

182. Before the time Plaintiff used Zantac products, Defendants impliedly warranted to their 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.

183. But Defendants failed to disclose that Zantac has dangerous propensities

when used as intended and that use of Zantac products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

184. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers of their Zantac products.

185. The Zantac products were expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendants.

186. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use Zantac products as marketed by Defendants, which is to say that Plaintiff was a foreseeable user of Zantac.

187. Defendants intended that Zantac products be used in the manner in which Plaintiff, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Zantac was not adequately tested or researched.

188. 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.

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

190. Defendants breached their implied warranty to Plaintiff in that Zantac products were not of merchantable quality, safe, or fit for their intended use, or adequately tested. Zantac has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

191. The harm caused by Defendants' Zantac products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

192. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff has sustained pecuniary loss and general damages in a sum

exceeding the jurisdictional minimum of this Court.

193. As a proximate result of the Defendants' breach of implied 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.

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

195. 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.

JURY TRIAL DEMAND

196. Plaintiff demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

197. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against the Defendants for:

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-judgment 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.

Dated: December 2, 2019

/s/ Jennifer A. Moore
Jennifer A. Moore, Esq. (State Bar No. 206779)
jennifer@moorelawgroup.com
MOORE LAW GROUP, PLLC
1473 South 4th Street
Louisville, KY 40208
Tel: (502) 717-4080
Fax: (502) 717-4086

Counsel for Plaintiff

/s/ Douglas A. Dellaccio
Douglas A. Dellaccio (AL Bar No.: asb-4578-l75d)
(Pro Hac Vice forthcoming)
Lauren S. Miller (AL Bar No.: asb-6193-v74n)
(Pro Hac Vice forthcoming)
CORY WATSON, P.C.
2131 Magnolia Avenue S.
Birmingham, AL 35205
Tel: (205) 328-2200
Fax: (205) 852-6299
ddellaccio@corywatson.com
lmiller@corywatson.com

Counsel for Plaintiff