UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SONJA O'NEAL, AS THE EXECUTRIX OF THE ESTATE OF RICHARD O'NEAL Plaintiffs, vs. BOEHRINGER INGELHEIM PHARAMCEUTICALS, INC., CHATTEM, INC., SANOFI-AVENTIS U.S. LLC, and SANOFI US SERVICES, INC., Defendants.	Civil Action No. 2:20-cv-00385 **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff, SONJA O'NEAL (hereinafter "Plaintiff") as the Executrix of the Estate of Richard O'Neal (hereinafter "Plaintiff-decedent"), by and through their undersigned counsel, for their Complaint allege as follows based on personal knowledge, investigation of counsel, and information and belief:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff-decedent as a direct and proximate result of the Defendants' negligent, fraudulent, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of Zantac, the brand- name version of the generic drug ranitidine.

PARTIES

Plaintiff

2. Plaintiff, Sonja O'Neal, is a citizen of the United States of America, and is a

resident of West Virginia.

3. At all relevant times, Plaintiff-decedent Richard O'Neal was a citizen of the United States of America, and was a resident of the State of West Virginia.

4. Plaintiff, Sonja O'Neal, is the wife of Plaintiff-decedent, Richard O'Neal.

5. Plaintiff-decedent Richard O'Neal began using Zantac on or about 2003 and until on or about January 2018.

6. As a direct and proximate result of ingesting Zantac, Plaintiff-decedent Richard O'Neal was diagnosed with esophageal cancer on or around December 20, 2017, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.

7. As a result of the foregoing, Plaintiff-decedent Richard O'Neal was caused to suffer sudden death on January 12, 2018.

8. Had Plaintiff-decedent been informed that taking Zantac would expose him to unsafe quantities of NDMA such that it could and did cause him to contract esophageal cancer, he never would have purchased or ingested Zantac. Plaintiff required and incurred expenses in connection with medical treatment as a result of these injuries, which were caused by Defendants' ranitidine-based Zantac products, and their unlawful conduct with respect to Zantac's design, manufacture, marketing, distribution, and sale. Plaintiff has endured pain, suffering, mental anguish, and sudden death as a result of his injuries, has suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

Defendants

Boehringer

9. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield,

Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about December 2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

Sanofi

10. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly-owned subsidiary of the French company Sanofi.

11. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly-owned subsidiary of the French company Sanofi.

12. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly-owned subsidiary of the French company Sanofi.

13. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") controlled the U.S. rights to over-the-counter Zantac from about January 2017 to the present and manufactured and distributed the drug in the United States during that period.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different States.

15. Venue is properly set in this District pursuant to 28 U.S.C. § 1391(b) and (c), since

Defendants transact business within, is found in, and/or has agents in this judicial district.

16. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants transact business within, is found in, and/or has agents in this district, such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

17. This court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process in that Defendants, acting through their agents or apparent agents, committed one or more of the following:

a. The transaction of any business within the state;

b. The making of any contract within the state;

c. The commission of a tortious act within this state; and

d. The ownership, use, or possession of any real estate situated within this state.

18. All of Plaintiffs' claims arise in part from conduct Defendants purposefully directed to Plaintiffs' home state. On information and belief, Defendants' Zantac was sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout Plaintiffs' home state.

19. Plaintiffs' claims arise out of Defendants' design, marketing, and sale of Zantac in Plaintiffs' home state.

20. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, Plaintiffs' home state.

21. Upon information and belief, at all relevant times, Defendants were present and doing business in Plaintiffs' home state.

22. At all relevant times, Defendants expected or should have expected that its acts

would have consequences within the United States of America, and Plaintiffs' home state in particular.

23. At all relevant times, Defendants placed Zantac into the stream of interstate commerce.

FACTUAL ALLEGATIONS

A Brief History of Zantac

24. Zantac was developed by GlaxoSmithKline and approved for prescription use by the FDA in 1983.[1] The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.[2]

25. Due in large part of 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."[3]

26. 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.

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

[2] *Histamine H2 Antagonist (Oral Route, Injection Route, Intravenous Route)*, MAYO CLINIC (last updated September 30, 2019), https://www.mayoclinic.org/drugs-supplements/histamine-h2- antagonistoral-route-injection-route-intravenous-route/description/drg-20068584.

[3] Wright, *supra* footnote 1.

27. At the time that ranitidine was developed, there was already existing scientific literature strongly suggesting that drugs like ranitidine, which contain a dimethylamine (DMA) group, are highly likely to form NDMA, when combined with other substances like, for example, nitrite found in the body. The dangers of NDMA formation from ranitidine should have been obvious to Defendants. For example, one taking Zantac would likely be doing so in connection with a meal. Many meals contain additional nitrates above that which is found naturally in the body. Bacteria found within the saliva and stomach, or enzymes in the body, can *reduce* the nitrates (NO_3) found in food into nitrites (NO_2). Additionally, some nitrites are found naturally in food or added as a preservative. Thus, at the time of ranitidine's discovery, Glaxo scientists should have known that the very events that would lead one to take Zantac, also put such person at risk of NDMA formation from Zantac due to increased nitrite levels in the body reacting with the ranitidine or its constituents.

28. Further, in 1981, the very year Zantac was launched commercially outside of the US, two exchanges in The Lancet, one of which involved Glaxo, discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H2 blocker, has a similar chemical structure to ranitidine. The Lancet was and is one of the most widely read and respected medical and scientific publications, and thus Defendants would have been aware of material related to ranitidine.

29. In one exchange, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, wrote into The Lancet describing how the researchers detected "mutagenic nitroso derivatives" in vitro for both cimetidine as well as ranitidine.[4] De Flora did recognize that his studies were in vitro, and that, as such, they weren't perfectly predictive of how ranitidine would

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

perform in humans.

30. In a second set of articles in The Lancet around the same time as the de Flora article, medical researchers from England discussed a study they performed on 140 human patients taking cimetidine. Their study observed that those who took cimetidine had a much higher level of N- nitrosamines than those in a control group who didn't take cimetidine.[5] In response, Roger Brimblecombe, a researcher from Smith Kline and French Research, Ltd.,[6] criticized the research performed by Reed and referenced unnamed "extensive studies" purportedly claiming that they demonstrate no "aetiological link between cimetidine treatment and the development of gastric cancer."[7] Importantly, Brimblecombe also stated that, "[t]he hypotheses raised by Reed and his colleagues are important and have been publicly and extensively discussed over the past two and half years. A great deal of research, both in our laboratories and in others, is in progress."[8] This clearly demonstrates that the formation of nitrosamines related to cimetidine and ranitidine, was one that was known to Glaxo and others, as it was a subject of much discussion in the scientific community at this time.

31. On December 5, 1981, Dr. Reed then responded to Brimblecombe, noting that, among other things, the studies Brimblecombe relied upon have been harshly criticized by others.[9] Reed also noted, "[d]ebate on N-nitroso compounds and human gastric cancer continues but some involvement seems likely . . . . If N-nitrosamine concentrations are raised in certain

[5] P. I. Reed, K. Haines, P.L.R. Smith, F.R. House, C.L. Walters, *Effect of Cimetidine on Gastric Juice N-Nitrosamine Concentration*, THE LANCET (Sept. 12, 1981).
[6] Smith Kline and French was part of the Smith Kline Beecham group, which merged with Glaxo in or around 2000. https://www.gsk.com/media/4573/300yrs-of-gsk.pdf (last visited Nov. 13, 2019). Smith Kline and French was the innovator and manufacturer of cimetidine (Tagamet). https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cimetidinetagamet.htm l (last visited Nov. 13, 2019).
[7] Roger Brimblecombe, *Cimetidine, Nitrosation, and Carcinogenicity*, THE LANCET at pp. 686-687 (Sep. 26, 1981).
[8] *Id.*
[9] P. I. Reed, K. Haines, C.L. Walters, S.L.R. Smith, and F.R. House, *Cimetidine, Nitrosation, and Carcinogenicity*, THE LANCET at pp. 1281-1282 (Dec. 5, 1981).

conditions with an increased risk of gastric cancer then this is a hint which must not be ignored."[10] Dr. Reed and his co-authors sounded the alarm on Zantac, but no one listened.

32. In 1983, a further study was published, this time specifically relating to ranitidine. Dr. Silvio de Flora and a group of researchers from the University of Genoa in Italy published a study specifically describing the formation of N-nitrosamines from ranitidine and an excess of nitrite under certain conditions.[11] On information and belief Defendants were aware of this study.

33. Further, also in 1983, yet another article was published specifically implicating the toxicity of ranitidine. Another group of Italian researchers from the University of Genoa discovered that in vitro, and under certain conditions, ranitidine had the tendency to form DNA-damaging nitroso compounds (like NDMA). Although the study was done on hamsters, and utilized conditions not necessarily identical to those that would be found in the human body, the study called for more research to be done into what conditions nitroso compounds formed as a result of ranitidine ingestion.[12] On information and belief Defendants were aware of this study.

34. Further evidence of Defendants' knowledge that Zantac formed NDMA in the body comes from a human study it was involved in and that was published in 1987.[13] In that study, the researchers tracked 15 patients who took ranitidine and had their gastric juice examined following ingestion of Zantac. Critically, instead of using the gold standard assay at the time (and which remains the case today) — mass spectrometry — to detect for the presence of nitrosamines in the human subjects, Glaxo used a nitrogen-oxide (i.e., nitric oxide, NO) assay which essentially

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[10] *Id.*

[11] Silvio De Flora, Carlo Bennicelli, Anna Camoirano, and Patrizia Zanacchi, *Genotoxicity of nitrosated ranitidine*, CARCINOGENESIS, Vol. 4, No. 3, pp. 255-260 (1983).

[12] Annalisa Maura, Albiana Pino, Luigi Robbiano, Enrica Cajelli, Renata Finollo, Marco Cavanna and Giovanni Brambilla, DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells, TOXICOLOGY LETTERS, 18, 97-102 (1983).

[13] *See* J Meyrick Thomas, JJ Misiewicz, AR Cook, MJ Hill, PLR Smith, CL Walters, JK Forster, LE Martin, and DF Woodings, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 28 GUT. At pp. 726-738 (1987).

was designed not to find nitrosamines.

35. Although the assay allegedly can detect N-nitrosamines, the sensitivity of the assay to detect NDMA is not established within the peer-reviewed literature. When the study team tested gastric fluid samples containing ranitidine, the nitrogen oxide assay indicated the presence of N- nitroso compounds (e.g., NDMA).[14] However, rather than exploring this further, the authors claimed that these results were "fals[e]" and then restricted all tests to "ranitidine free samples," to avoid high readings of N-nitroso compounds.[15] Upon information and belief, these results were not false, and in fact, were a warning sign to Defendants that ranitidine did generate carcinogenic N- nitroso compounds like NDMA. Scientists at Valisure have demonstrated that when ranitidine is incubated in simulated gastric fluid with nitrite, high levels of NDMA are formed. However, rather than exploring this issue further, the study team simply did not test any study samples that had ranitidine in them.

36. In fact, on information and belief, Glaxo never used a mass spectrometry assay to test for the presence of nitrosamines in this study, or, in any of the studies and trials it did in connection with its trials associated with its ranitidine NDA. That is because, as explained above, when using GC/MS (which requires heating of up to 130 degrees Celsius), excessive amounts of nitrosamines are formed. And, had Glaxo used a GC/MS assay, which would have necessarily resulted in the formation of large amounts of NDMA, the FDA would never have approved Zantac as being safe.

Zantac's Commercial Success

37. Zantac was approved for prescription use by the FDA in 1983.[16] Due in large part

[14] *Id.* at p. 730.
[15] *Id.*
[16] Wright, *supra* footnote 1, at 26

to Glaxo's marketing strategy, Zantac was a tremendously successful drug, reaching $1 billion in total sales in December 1986.[17] 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."[18] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[19] Indeed, Zantac has been marketed as a safe and effective treatment for gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.

38. Zantac became available without a prescription in 1996,[20] and generic versions of the drug (ranitidine) became available the following year.[21] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[22] 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[23]—a 3.1% increase from the previous year.[24]

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

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

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[17] *See id.* at 27.
[18] *See id.* at 25.
[19] *See id.* at 27.
[20] *Id.* at 28
[21] David Ranii, *Generic Zantac on market*, NEWS AND OBSERVER (Aug. 5, 1997).
[22] *GlaxoSmithKline – Product Portfolio*, PHARMACEUTICALS COMPANY ANALYSIS (Jan. 2003) (Lexis Advance)
[23] *Leading antacid tablet brands in the United States in 2018*, *supra* footnote 3.
[24] *Sales growth of leading brands of antacid tablets in the United States in 2018 (change to prior sales year)*, STATISTA (last visited Nov. 13, 2019), https://www.statista.com/statistics/194547/us-sales- growth-of-antacid-tablet-brands-in-2013/.

41. Zantac became available without a prescription in 1996,[25] and generic versions of the drug (ranitidine) became available the following year.[26] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[27] Zantac sales 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[28] – a 3.1% increase from the previous year.[29]

42. Over the past 20 years, the rights to Zantac in the U.S. have changed hands several times. In 1996, Zantac was first approved by the FDA for over-the-counter sale. At that time, the over-the-counter version was sold by a joint venture between Glaxo and Warner-Lambert, formed to market Zantac and other over-the-counter drugs.[30] That joint venture ended in 1998, with Warner-Lambert (which was acquired by Pfizer) retaining the right to market Zantac.[31] Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006,[32] and manufactured and sold the drug in the United States from approximately January 2007 to January 2017.[33]

43. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and had since that time been manufacturing and selling the over-the-counter version of the drug in the United States.[34] Since its launch in 1983, Glaxo sold the prescription version of Zantac.

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[25] Wright, *supra* footnote 1, at 28.
[26] David Ranii, *Generic Zantac on market*, NEWS AND OBSERVER (Aug. 5, 1997).
[27] *GlaxoSmithKline – Product Portfolio,* PHARMACEUTICALS COMPANY ANALYSIS (Jan. 21, 2003).
[28] *Sales growth of leading brands of antacid tablets in the United States in 2018 (change to prior sales year)*, STATISTA (last visited Sept. 13, 2019), https://www.statista.com/statistics/194547/us-salesgrowth-of-antacid-tablet-brands-in-2013/.
[29] *Id.*
[30] *Business Briefs: Warner-Lambert Increases OTC Stake*, American Health Line (Dec. 20, 1995) (available through Lexis Advance)
[31] *Warner-Lambert/Glaxo: To End Joint Venture*, American Health Line (Aug. 4, 1998) (available through Lexis Advance)
[32] *Boehringer Ingelheim Pharmaceuticals, Inc. Announces Agreement to Acquire Zantac® from Johnson & Johnson and the Pfizer Consumer Healthcare Business,* BUSINESS WIRE (Oct. 12, 2006).
[33] *See Digesting an acquisition: Patrick Hennig, Boehringer Ingelheim; Ingelheim Pharmaceuticals to acquire U.S. rights for Zantac product line; Interview*, DRUG STORE NEWS (Mar. 5, 2007); Mike Pare, *Chattem adds Zantac, Dulcolax to portfolio*, CHATTANOOGA TIMES FREE PRESS (TENNESSEE) (Feb. 8, 2017).
[34] [34] *Id.*, *Chattem adds Zantac.*

A. Throughout the relevant period, and throughout each period of time each Defendant marketed and sold Zantac, the scientific community continued to raise concerns about NDMA formation from ranitidine.

44. As set forth above, even before ranitidine's launch, and shortly after its launch, serious questions were raised about the safety of ranitidine. Specifically, questions were raised as to whether ranitidine ingestion can lead to the formation of highly carcinogenic NDMA within the human body. As time went on, the scientific evidence establishing that NDMA is formed from ranitidine, in the body, and in other conditions, continued to pile up.

45. For example, a 2011 scientific study found that, out of eight pharmaceuticals that were observed, "ranitidine showed the strongest potential to form N nitrosodimethylamine (NDMA)" when present in drinking water during chloramine disinfection.[35] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[36] On information and belief, the Defendants were aware of this study. Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[37] On information and belief, the Defendants were aware of this study.

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

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

[36] *Id*. at 948.

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

precursors."[38] On information and belief, the Defendants were aware of this study.

47. A peer-reviewed study published in the scientific journal Carcinogenesis in 2016 "confirmed the production of N-nitrosodimethylamine (NDMA), a potent carcinogen, by nitrosation of ranitidine under stomach-relevant pH conditions in vitro" and also showed that, during the 24 hours following ranitidine intake, the quantity of NDMA in urine excreted by the patient "increased 400 folds from 110 to 47 600 ng."[39] The article noted that these levels of NDMA "equaled or exceeded those observed previously in patients with schistosomiasis, a disease wherein N nitrosamines are implicated as the etiological agents for bladder cancer."[40] The article also cautioned that these "estimates are conservative": The actual exposure to NDMA is "likely much higher than that eliminated in urine" since NDMA has "a high metabolic conversion rate" so that only about 0.05% of NDMA in the body is excreted in urine.[41] The authors of the study concluded that "a more comprehensive risk assessment"—such as "[e]pidemiological studies evaluating cancer risk, particularly bladder cancer, attributable to the long term use of ranitidine"— was needed because of "the widespread use of ranitidine."[42] The authors also noted that "alternative medications, such as proton pump inhibitors (PPIs), would less likely promote in vivo nitrosation because of the lack of amines in their structure."[43] On information and belief, the Defendants were aware of this study.

48. A January 2018 scientific review "summariz[ing] major findings over the last decade related to N Nitrosodimethylamine (NDMA)" again pointed out that ranitidine had a high

[38] Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study*, 48 ENVTL. SCI. & TECHNOLOGY 8653 (June 26, 2014).
[39] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of* N- *nitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).
[40] *Id.*
[41] *Id.*at 632.
[42] *Id.*at 632-633.
[43] *Id.*

rate of NDMA formation "upon chloramination."[44] On information and belief, the Defendants were aware of this study.

49. Not only was there a significant amount of scientific literature that continued to pile up establishing NDMA formation from ranitidine, but studies were also published specifically linking Zantac to certain types of cancers in humans. For example, in 2004 an extensive epidemiology study was published specifically linking Zantac use to bladder cancer.[45] In that study, nearly 51,000 health professionals (such as dentists, veterinarians, pharmacists) were studied over nearly 15 years to assess the relationship between peptic ulcer disease and bladder cancer. As part of that study, the study participants' use of H_2 blockers (which included both cimetidine and Zantac), were monitored. The study's authors noted that for those participants who took either cimetidine or Zantac, "[w]e observed an increase in bladder cancer risk among men who reported taking either of these medications . . . ."[46]

50. Despite the undeniable scientific evidence linking ranitidine to the production of high levels of NDMA, or, the mounting evidence that Zantac itself is linked to cancer, Defendants did not disclose this link to consumers on Zantac's label or through any other means. Since Zantac has been commercially available, by prescription and over-the-counter, the FDA has never been presented with any disclosure by any Defendant, concerning the risk of NDMA formation from ranitidine. Surely, if it had, the FDA would never have approved the drug for use.

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[44] Massimiliano Sgroi, et al., N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review on formation and removal, 191 CHEMOSPHERE 685-703 (Oct. 15, 2017).

[45] Dominque S. Michaud, Pauline A. Mysliwiec, Walid Aldoori, Walter C. Willet, and Edward Giovannucci, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION, Vol. 13 250-254 (Feb. 2004).

[46] *Id.* at 252.

Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA), ENVIRONMENTAL PROTECTION AGENCY (Jan. 2014), https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf.

B. Dangers of N-Nitrosodimenthylamine (NDMA)

51. "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens."[47]

52. 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."[48] NDMA is no longer produced or commercially used in the United States, except for research.[49] In other words, it is only a poison.

53. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[50] 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."[51]

54. 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

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[47] *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)*, ENVIRONMENTAL PROTECTION AGENCY (Jan. 2014), https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf.

[48] 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"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents*, 405 MUTATION RESEARCH 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumours of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[49] *Technical Fact Sheet*, *supra* footnote 47.

[50] *Technical Fact Sheet*, *supra* footnote 47; World Health Organization, *N- Nitrosodimethylamine (NDMA)*, GUIDELINES FOR DRINKING-WATER QUALITY (3rd ed. 2008) [hereinafter *WHO Guidelines*], *available at* https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[51] *WHO Guidelines*, *supra* footnote 50.

See, e.g., Karen De Witt, *Carcinogen Fear Allayed*, THE NEW YORK TIMES (July 2, 1980) (reporting recall of beer that contained higher level of nitrosamines than that permitted by FDA).

FDA.[52]

55. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—valsartan, losartan, and irbesartan—because the medications "contain[ed] nitrosamine impurities that don't meet the [FDA's] safety standards,"[53] which provide that the intake of NDMA should be no more than 96 ng.[54] 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.[55] In the case of valsartan, the NDMA was an impurity caused by a manufacturing defect, and thus NDMA was present in only *some* valsartan products.

56. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying the FDA's GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan[56] —the level of NDMA in Zantac is 2,511,469 ng per Zantac tablet—**124 times** more than the highest amount detected in the recalled valsartan.[57]

57. Moreover, unlike valsartan, the high levels of NDMA that Zantac produces are not caused by a manufacturing defect but rather 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."[58] Thus,

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[52] *See, e.g.*, Karen De Witt, *Carcinogen Fear Allayed*, THE NEW YORK TIMES (July 2, 1980) (reporting recall of beer that contained higher level of nitrosamines than that permitted by FDA).

[53] *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, FDA (May 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/recalls- angiotensin-ii- receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan.

[54] *FDA Updates and Press Announcements*, *supra* footnote 13.

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

[56] *Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace*, FOOD & DRUG ADMINISTRATION (Jan. 25, 2019), https://www.fda.gov/ media/117843/download.

[57] *See* Exhibit A at 5; *Combined N-Nitrosodimethylamine*, *supra* footnote 83.

[58] Exhibit A at 19.

ranitidine produces NDMA by "react[ing] with itself,"[59] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[60]

58. NDMA in and of itself is toxic. But, NDMA is not the final harmful metabolite produced from ranitidine. NDMA itself is further metabolized by the body into other harmful compounds. For example, it is well-established that NDMA is metabolized by the body into formaldehyde. Formaldehyde is a *known* carcinogen.[61] IARC classifies something as a known carcinogen when "there is sufficient evidence of carcinogenicity in humans."[62] In addition to IARC's designation of formaldehyde as a known carcinogen, the United States itself has designated fomaldehyde as a known carcinogen. In 2014, The National Toxicology Program, a division of the U.S. Department of Health and Human Services, classified formaldehyde as a known human carcinogen.[63] Formaldehyde has been specifically linked to various types of cancers. In 2009, IARC stated that "there is sufficient evidence for a causal association of formaldehyde with leukemia."[64]

59. At all times relevant to this complaint, there was never any debate about the toxicity and lethality of NDMA. However, at one time, long ago, much of the literature linking NDMA to cancers, were based on animal studies. And, such studies linked NDMA to carcinogenesis and other adverse health consequences. In one example referenced above, a news article published in 1979 (four years prior to Zantac's launch), noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."

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[59] Exhibit A at 2.

[60] *Id.* at 1.

[61] https://www.cancer.org/cancer/cancer-causes/formaldehyde.html (last visited Nov. 13, 2019).

[62] https://monographs.iarc.fr/wp-content/uploads/2019/07/Preamble-2019.pdf, at p. 35 (last visited Nov. 13, 2019).

[63] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r3 (last visited Nov. 13, 2019).

[64] https://www.atsdr.cdc.gov/toxprofiles/formaldehyde_addendum.pdf, at p. 47 (last visited Nov. 13, 2019).

60. The NDMA levels associated with Zantac pose an extreme risk to cancer in humans. In the FDA's press releases related to the various angiotensin receptor blocker recalls, the FDA modeled some cancer risks associated with the amount of NDMA found in the ARB medications. For example, the FDA stated, "FDA scientists estimate that if 8,000 people took the highest valsartan dose (320 mg) from the recalled batches daily for the full four years, there may be one additional case of cancer over the lifetimes of these 8,000 people."[65] As stated above, the highest level of NDMA detected with respect to the ARB medicines was 20,190 ng. Given that NDMA levels in urine of those in the Mitch and Zeng Study who took Zantac was 47,000 ng, and that amount likely represents only 0.5% of the amount of NDMA formed in the body from a Zantac tablet, using the FDA's calculations, the cancer risks of those who take Zantac are *well* below 1 in 4000.

C. Defendants did not disclose to Plaintiffs, the FDA or anyone else that Zantac exposes users to high levels of the carcinogen NDMA, despite having actual or constructive knowledge of this fact.

61. During the time that Defendants manufactured and sold over-the-counter Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. At no time did any Defendant ever disclose this risk to consumers on the drug's label, or through any other means, nor did Defendants report these risks to the FDA. Further, no Defendant presented to the FDA a proposed label disclosing the risks for NDMA formation from ranitidine, and therefore, the FDA never ruled upon any proposed label disclosing the NDMA risk.

62. Valisure, LLC is an online pharmacy currently licensed in 38 states and an

[65] https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps (last visited Nov. 13, 2019).

analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and the FDA (FEI #: 3012063246). Valisure's mission is to help ensure the safety, quality and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

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

64. Valisure submitted its Citizen's Petition (the "Petition") to the FDA on September 9, 2019. A copy of the Petition is attached as Exhibit "A".

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

66. As the Petition points out, in vivo studies have strongly suggested ranitidine's formation of NDMA and carcinogenicity for decades. For example, a 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, ranitidine administered with nitrite resulted in a "significant DNA fragmentation."[66] Thereafter, in 1983, another study published in the journal Carcinogenesis titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically

[66] Brambilla, G., Cavanna M., De Flora S. (1982). Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance. In: Nicolini C. (eds) Chemical Carcinogenesis. NATO Advanced Study Institutes Series (Series A: Life Sciences), Vol. 52. Springer, Boston, MA (https://link.springer.com/chapter/10.1007/978-1-4684-4334-9_11).

suspected the carcinogenic nature of ranitidine in combination with nitrite.[67] 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."[68]

67. Despite the undeniable scientific evidence linking ranitidine to the production of high levels of NDMA, Defendants did not disclose this link to consumers on Zantac's label or through any other means.

68. Defendants have had notice of serious adverse health outcomes regarding cancer and other injuries associated with their ranitidine products, including Zantac, through case reports, clinical studies and post-market surveillance.

69. As such, these numerous reports of cancer put Defendants on notice as to the excessive risks of injuries related to the use of ranitidine products, including Zantac, and yet those products remain easily accessible to consumers such as Plaintiff.

70. Moreover, there are reasonable alternative treatments available to treat the conditions indicated by Zantac, such as another histamine blocker or a proton-pump inhibitor (PPI). Indeed, as the Petition notes, there were numerous alternative medications that Valisure tested where NDMA was not detected.[69]

71. Defendants knew or should have known that Zantac exposed users to unsafe levels of the carcinogen NDMA based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics,

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

[68] Exhibit A at 11.

[69] *Id.* at 15-16.

pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

72. Despite their knowledge that exposure to unsafe levels of NDMA could result in cancer, Defendants took no action to inform Plaintiff, Plaintiff's physicians and/or the FDA of this known risk. Instead, Defendants continued to represent that their ranitidine products, including Zantac, had been tested and were found to be safe and effective for their indicated use in treating gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions. Defendants promoted and marketed ranitidine products, including Zantac, as safe and effective for individuals such as Plaintiff-decedent throughout the United States, including West Virginia.

73. Defendants negligently and/or recklessly failed to disclose their knowledge that their ranitidine products, including Zantac, contained unsafe levels of NDMA that could cause cancer, from Plaintiff, Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

74. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with ranitidine products, including Zantac, including, but not necessarily limited to, long-term usage and the cumulative effects of long-term usage.

75. In omitting and inadequately providing critical safety information regarding the use of ranitidine products, including Zantac, in order to induce their purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff.

76. Despite notice and knowledge that ranitidine products, including Zantac, contained unsafe levels of NDMA which can cause cancer and other severe health problems, Defendants continued to market and sell ranitidine products, including Zantac, without warning consumers,

healthcare providers, and/or the FDA of these significant risks.

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

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

79. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to Plaintiff's ingestion of Zantac, which caused Plaintiff to suffer from cancer and any and all sequelae.

80. Defendants misrepresented and failed to disclose risks of cancer and other injuries associated with Zantac with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Zantac or ranitidine for the treatment of gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare.

81. As a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.

82. Consequently, Plaintiffs seeks compensatory damages as a result of Plaintiff-decedent's use of Zantac, which has caused Plaintiff to suffer from esophageal cancer as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health

consequences.

D. Most global health regulators, and manufacturers themselves, have recalled their Zantac and ranitidine products.

83. Since the filing of the Valisure's Citizen Petition on September 9, 2019, virtually every health regulator throughout the world, with the exception of the U.S. FDA, has taken steps to remove Zantac and ranitidine from the marketplace. In addition, many manufacturers, including the Boehringer and Sanofi Defendants, have also recalled the drug.

84. At the request of Health Canada, the department of the Canadian government responsible for national public health, "companies marketing ranitidine products in Canada have stopped any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels."[70] According to Canadian regulators, "[c]urrent evidence suggests that NDMA may be present in ranitidine, regardless of the manufacturer."[71]

85. Similarly, South Korea's Ministry of Food and Drug Safety has stated that "[i]t suspects NDMA may have been unintentionally produced in the course of natural decomposition and synthesis reactions of the nitrite and dimethylamine chemicals in ranitidine or by dimethylamine accidentally being added during the manufacturing process."[72]

86. Germany, Switzerland, and Austria all have initiated recalls of ranitidine-based drugs,[73] and Finland has withdrawn drugs containing ranitidine from its pharmacies.[74] Singapore

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[70] *Information Update – Health Canada requests that companies stop distributing ranitidine drugs in Canada while it assesses NDMA; some products being recalled*, CISION CANADA (Sept. 17, 2019), https://www.newswire.ca/news-releases/information-update-health-canada- requests-that-companies- stop-distributing-ranitidine-drugs-in-canada-while-it-assesses-ndma- some-products-being-recalled-821911993.html.

[71] *Id.*

[72] *Korea bans sales of Zantac and other ranitidine drugs after carcinogen alert*, Pulse (Sept. 26, 2019), https://m.pulsenews.co.kr/view.php?year=2019&no=769561.

[73] Tom Gallen, *Ranitidine Recalls Begin In Europe As Regulators Take Action*, PHARMA INTELLIGENCE (Sept. 18, 2019), https://hbw.pharmaintelligence.informa.com/RS149219/Ranitidine-Recalls-Begin- In-Europe-As- Regulators-Take-Action.

[74] *Pharmacies pull heartburn meds over contamination concerns*, UUTISET (Sept. 19, 2019),

has suspended the sale and supply of several brands of ranitidine.[75] Qatar's Ministry of Public Health "has withdrawn samples of ranitidine, including the one commercially known as Zantac, from public and private pharmacies" and has "recommend[ed] patients who use these drugs to review and consult their doctor, and those who use them without a prescription should use other alternatives."[76] In addition to these countries, the following countries have either issued recalls, medical alerts, announced an investigation, or companies voluntarily recalled their Zantac and/or generic ranitidine: Australia, Bangladesh, Bahrain, Cyprus, Denmark, Egypt, France, Greece, Hong Kong, India, Ireland, Jamaica, Kenya, Kuwait, Italy, Japan, Libya, Lithuania, Morocco, New Zealand, Namibia, Norway, Oman, Pakistan, Saudi Arabia, South Africa, Suriname, Taiwan, Trinidad and Tobago, UAE, UK, and Vietnam, among others.[77]

87. Some companies that manufacture and distribute Zantac and generic ranitidine also have taken action to protect consumers. Most recently, on November 6, 2019, DA issued a recall notice for ranitidine distributed nationally by Aurobindo Pharma USA and AuroHealth between September 28, 2018 and September 19, 2019.[78] Additionally, on October 18, 2019, Zantac's current manufacturer, Defendant Sanofi, issued a recall of its Zantac in the U.S. and Canada.[79] In its release announcing the recall, Sanofi stated that "Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. and Canadian products, Sanofi has made the decision to conduct

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https://yle.fi/uutiset/osasto/news/pharmacies_pull_heartburn_meds_over_contamination_conce rns/10977530.

[75] *Singapore halts sales of some antacids over stomach cancer concerns*, SOUTH CHINA MORNING POST (Sept. 16, 2019), https://www.scmp.com/news/asia/southeast- asia/article/3027521/singapore-halts-sales-some-antacids-over-stomach-cancer.

[76] *Health ministry recalls Zantac as a precautionary measure*, QATAR TRIBUNE (Sept. 16, 2019), http://www.qatar-tribune.com/news-details/id/172460.

[77] https://www.valisure.com/blog/uncategorized/detection-of-ndma-in-raniditine/ (last visited Nov. 13, 2019).

[78] https://www.newsweek.com/zantac-recall-ranitidine-heartburn-drug-cancer-fears-1470591 (last visited Nov. 13, 2019).

[79] https://www.usatoday.com/story/news/health/2019/10/18/sanofi-recalls-heartburn-drug- zantac-investigate-carcinogen/4021833002/ (last visited Nov. 13, 2019).

the voluntary recall in the U.S. and Canada as the investigation continues."[80] On October 9, 2019, Glaxo announced that it was pulling its Zantac product from the marketplace worldwide.[81] Sandoz, a unit of Novartis AG, has stopped its "worldwide distribution of generic versions" of Zantac.[82] And Dr. Reddy's Laboratories Limited has suspended its supply of generic Zantac (ranitidine) worldwide.[83]

88. Other large pharmacies in the U.S. have also pulled Zantac and generic equivalents from their shelves. On September 30, 2019, pharmacy giants CVS, Walgreens, and Rite-Aid announced they were pulling Zantac and generic ranitidine from their shelves.[84] Walmart also announced that it was pulling the drug from its shelves.[85]

89. The United States drug regulatory system is largely, if not entirely, reliant on the drug manufacturers themselves to perform adequate testing and report adverse events. 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 Citizens Petitions) to bring new information about an approved drug like Zantac to the agency's attention.

90. 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:

> The report is required to contain . . . [a] brief summary of significant new

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[80] *Id.*

[81] https://www.fiercepharma.com/manufacturing/gsk-joins-other-drugmakers-recalling-zantac-products (last visited Nov. 13, 2019).

[82] Anna Edney, *Carcinogen Scare Sets Off Global Race to Contain Tainted Zantac*, BLOOMBERG (Sept. 18, 2019), https://www.bloomberg.com/news/articles/2019-09-18/sandoz- halts-distribution- of-zantac-after-carcinogen-concerns.

[85] https://www.cnn.com/2019/09/30/health/cvs-zantac-pulled-cancer-trnd/index.html.

[83] *Dr Reddy tumbles on buzz of halting worldwide supply of Ranitidine*, BUSINESS STANDARD (Sept. 23, 2019), https://www.business-standard.com/article/news-cm/dr-reddy-tumbles-on-buzz- of- halting-worldwide-supply-of-ranitidine-119092300347_1.html.

[84] https://www.washingtonpost.com/health/2019/09/30/drugstores-are-pulling-zantac-like- heartburn-drugs-off-shelves-over-potential-cancer-risk/.

[85] https://www.cnn.com/2019/09/30/health/cvs-zantac-pulled-cancer-trnd/index.html.

> 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.[86]

91. The manufacturer's annual report also must contain "[c]opies 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."[87]

92. Defendants simply 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. Further, the FDA simply doesn't have the resources to police and enforce this provision.

93. 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.

PLAINTIFF'S USE OF ZANTAC AND RESULTING HARM

94. Plaintiff is and was at all times alleged herein a citizen of the State of West Virginia.

95. Plaintiff-decedent ingested Zantac on numerous occasions, including but not limited to, in or about 2003 through 2018.

96. Plaintiff read and followed the directions regarding the use of Zantac and would not have used Zantac had he been properly appraised of the risks associated with the use of Zantac.

97. Plaintiff was diagnosed with esophageal cancer on December 20, 2017 after taking

[86] 21 C.F.R. § 314.81(b)(2)(i).

[87] 21 C.F.R. § 314.81(b)(2)(v).

Zantac from about 2003 through 2018.

TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Discovery Rule Tolling

98. Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, that high levels of the carcinogen NDMA was produced by Zantac ingestion.

99. Plaintiff did not know of or discover facts that would have caused a reasonable person to suspect that his injuries were caused by Zantac, or by Defendants' concealment of the fact that high levels of NDMA were produced by Zantac. The information linking Zantac to NDMA was contained exclusively in articles that were published in scientific journals. Plaintiff did not have access to these scientific articles because they were behind a paywall. And even had the articles been more widely available, the significance of these highly technical articles would not have been apparent to Plaintiff.

100. Plaintiff could not have reasonably discovered the true extent of Defendants' deception about Zantac's safety until Valisure filed its Citizen Petition disclosing the extremely high levels of NDMA produced by Zantac.

101. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent Concealment Tolling

102. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment throughout the period relevant to this action of Zantac's producing high levels of the carcinogen NDMA.

103. Instead of disclosing to consumers the link between Zantac and the carcinogen

NDMA, Defendants continued to manufacture and sell Zantac without disclosing this information on the drug's label or elsewhere. Further, Defendants misled the public into believing Zantac was safe by repeatedly touting the safety of Zantac.

C. Estoppel

104. Defendants were under a continuous duty to disclose to Plaintiff the risk of NDMA exposure associated with Zantac.

105. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Zantac and never updated the drug's label to disclose this risk.

106. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Continuing Tort

107. The continuing tort doctrine applies when there is a repeated or continuous injury and the tort is not completed until the last injury is inflicted or the wrongdoing ceases. In cases of continuing torts, the statutes of limitations do not begin to run until the date of the last tortious act.

108. The Plaintiff used Zantac over extended periods. Each time a Plaintiff ingested Zantac, it constituted a continuing tort.

109. The time period associated with the Plaintiff's statute of limitations did not begin to run until, at the earliest, the Plaintiff's last use of Zantac.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

110. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

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

112. Defendants manufactured, marketed, distributed, and sold Zantac during the periods set forth above.

113. Defendants manufactured, designed, marketed, distributed, and sold Zantac with the expectation of reaching consumer, Plaintiff-decedent Richard O'Neal, without any alternations or changes.

114. The Zantac manufactured, designed, marketed, distributed, and sold by Defendants was defective in design or formulation, because when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

115. The Zantac manufactured, designed, marketed, distributed, and sold by Defendants was defective in design or formulation, because when it left the hands of the Defendants, it was more dangerous than an ordinary consumer would expect.

116. Zantac is unreasonably dangerous and unsafe for its intended purpose because, when ingested, it forms extremely high levels of NDMA and other harmful metabolites in the body. NDMA is a human carcinogen associated with various types of cancers. Indeed, the chemical structure of ranitidine itself is inherently unstable, and contains the two chemical precursors to the formation of NDMA: a nitrite group and a dimethylamine (DMA) group.

117. The foreseeable risks of Zantac include an increase in the occurrence of cancer from exposure to Zantac and NDMA.

118. The fact that harm such as that suffered by Plaintiff-decedent will occur from use of Zantac is completely foreseeable because Zantac ingestion causes high quantities of NDMA to form in the human body. Further, NDMA itself metabolizes into other harmful compounds including, but not limited to, formaldehyde, a known human carcinogen and known to cause leukemia.

119. The likelihood that cancer would result from the use of Zantac is very high, based upon the fact that Defendants knew that the likelihood and severity of the harm associated with Zantac usage was great. At least thousands of patients who took Zantac, including Plaintiff, experienced cancers proximately caused by Zantac use or have been exposed to an unreasonable risk of developing cancer. The likelihood and severity of the cancers suffered by Plaintiff and other users of Zantac far outweighed the Defendants' burden in taking safety measures to reduce or avoid the harm.

120. Zantac, as manufactured, designed, marketed, distributed, and sold by Defendants is much more dangerous than an ordinary consumer would expect in that it produced hazardous amounts of NDMA and other harmful metabolites when ingested in the body.

121. At the time Defendants manufactured, designed, marketed, distributed, and sold Zantac to Plaintiff-decedent, safer, more practical, alternative designs were available to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease, including but not limited to prescription drug alternatives such as Pepcid, Prilosec, Nexium, Prevacid, Protonix, AcipHex, and Dexilant, which pose much less risk of cancer with comparable or adequate efficacy. Indeed, these drugs, which are intended to treat the same condition as Zantac is intended to treat, don't metabolize into NDMA when ingested.[88]

122. The Zantac manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, as alternative formulations for [these types of meds] were available with comparable or adequate efficacy that did not pose the same cancer risk.

123. The risks of NDMA formation in the human body from Zantac ingestion, and the concomitant risk of cancers associated with NDMA, were actually known to and foreseeable to all

[88] Exhibit A at 15–16.

Defendants at all times during the period which they manufactured and sold Zantac. Even before Zantac was commercially launched in 1983 in the United States, as further described above, the scientific community expressed concern about the propensity of ranitidine to form NDMA in the body when ingested. Further, from the time of Zantac's launch until the present day, various scientific literature, as further described in this complaint, expressed concerns about NDMA formation from ranitidine. Plaintiff was unaware of this scientific literature, but Defendants were aware of it.

124. The Defendants could have reduced or prevented the foreseeable risks of harm associated with Zantac by adopting a reasonable and feasible alternative design.

125. The likelihood and severity of the cancers suffered by patients like Plaintiff far outweighed the Defendants' burden in taking safety measures to reduce or avoid the harm. Given the sheer number of people taking Zantac, including over the long-term, there was a high likelihood that Zantac would injure a very large number of patients, by causing cancer in such patients, which would be severely detrimental to one's health and could result in death.

126. The Defendants knew that ordinary patients would use Zantac without knowledge of the hazards involved in such use. Zantac failed to perform as an ordinary consumer would expect in that it produced hazardous amounts of NDMA and other harmful metabolites when ingested in the body.

127. The Defendants knowingly designed Zantac with the design defect that causes Zantac to form NDMA in the body when ingested, to maximize profits.

128. Zantac was approved by the FDA in 1983 pursuant to New Drug Application 0180703. Following the filing of NDA 0180703, there were numerous other NDAs filed by the Defendants, including, but not limited to, NDA Nos. 019090 (Glaxo Zantac injection), 019675

(Glaxo Zantac syrup), 020095 (Glaxo Zantac 150 capsule), 020251 (Glaxo Zantac effervescent 150), 021698 (Sanofi Zantac 150), 0200095 (Glaxo Zantac 300 tablet), 020520 (Sanofi Zantac 75 tablet), and 020745 (Sanofi Zantac 75 effervescent). In connection with each of these NDAs, the relevant Defendant which filed such NDA could have submitted an alternative or different formulation for Zantac, one in which Zantac wouldn't metabolize into NDMA and other harmful metabolites. But, no Defendant did so, instead, continuing to utilize the defective design of ranitidine, which caused the formation of NDMA and other harmful metabolites in the body upon ingestion.

129. The benefit in promoting enhanced accountability through strict products liability outweighs the benefit of a product that the Defendants should have and could have made safer years earlier.

130. Had Plaintiff known of the defect in Zantac, he would not have taken Zantac. Instead, he would have taken a safer alternative to Zantac that wouldn't expose him to harmful levels of NDMA and other dangerous metabolites.

131. Plaintiff ingested Zantac for an approved purpose and experienced cancers as a result of his Zantac use.

132. Based on the foregoing, the Zantac manufactured, designed, marketed, distributed, and sold by Defendants was defective in design at the time it left Defendants' control.

133. As a direct and proximate result of the defective design of Zantac manufactured by Defendants and consumed by Plaintif-decedent, Plaintiffs suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future. Plaintiffs

suffered injuries and damages as described, in excess of $75,000.00.

134. 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

135. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

136. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Zantac.

137. It was reasonably foreseeable that Plaintiff would ingest Zantac.

138. The Zantac manufactured, designed, marketed, distributed and sold by Defendants was defective due to inadequate warning or instruction, because at the time it left the control of Defendants and was supplied to Plaintif-decedent, Defendants knew or should have known that their product was unreasonably dangerous as confirmed by the extensive body of published literature and its own internal data, because Zantac substantially and significantly increases the risk of cancer compared to other treatment options for gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.

139. Despite the fact that Defendants knew or should have known about the increased risk of cancer with Zantac as compared to other treatment options for gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease, Defendants failed to exercise reasonable care to adequately warn of the increased cancer risk.

140. Indeed, at the time the Defendants manufactured and sold Zantac, the scientific community had already identified the dangers of NDMA formation in ranitidine. 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.

141. The Zantac manufactured and supplied by Defendants was defective due to inadequate warning or instruction, because at the time it left the control of Defendants and was supplied to Plaintiff-decedent, Defendants knew or should have known that their product was unreasonably dangerous, as confirmed by the extensive body of published literature and its own internal data, because Zantac substantially and significantly increases the risk of cancer.

142. Zantac posed a substantial danger to patients' bodies because NDMA forms in high quantities in the human body as a result of Zantac ingestion. Further, NDMA itself metabolizes into other harmful compounds including, but not limited to, formaldehyde, a known human carcinogen and known to cause leukemia.

143. Even though Defendants knew or should have known about the increased risk of cancer with Zantac use, Defendants failed to exercise reasonable care to adequately warn of the increased cancer risk with Zantac use. In fact, Defendants made no reference in the Zantac label to the formation of high quantities of NDMA when ingested in the human body, and that NDMA leads to cancers in animals and humans.

144. Ordinary consumers and physicians would not have recognized, and did not recognize, the risks Zantac posed to patients. The significantly increased risk of harm from cancer due to Zantac and NDMA is not an open and obvious danger or a matter of common knowledge.

145. The Defendants failed to adequately warn Plaintiff about the risks that Zantac posed

to consumers.

146. The Zantac manufactured and supplied by Defendants was also defective due to inadequate post-marketing warning or instruction, because after Defendants knew or should have known of the substantially increased risks as described above, Defendants failed to provide adequate post-market or post-approval warnings to consumers and/or their healthcare providers and/or the FDA, which they have authority to do as the holder of the NDAs, and failed to revise the Zantac label to warn of the serious and substantially increased risk of cancer caused by Zantac as compared to other H2-receptor antagonists when taken as prescribed; nor did Defendants warn Plaintiff-decedent or his physician or the FDA that alternative safer options were available.

147. The Defendants never warned the FDA, those who took Zantac, or the scientific and medical communities, that NDMA forms in high quantities when ingested in the human body, and that NDMA leads to cancers in animals and humans.

148. Plaintiff was injured by using Zantac in a reasonably foreseeable way.

149. The lack of adequate warnings and instructions was a substantial factor in causing Plaintiffs' injuries.

150. Had Defendants adequately warned and instructed Plaintiff, he would not have taken Zantac, and would not have developed the cancer he has been afflicted with. Instead, Plaintiff would have taken an alternative drug to Zantac that would not have exposed him to harmful levels of NDMA and other dangerous metabolites.

151. Plaintiff's cancer-related injuries were directly and proximately caused by Defendants' inadequate warnings.

152. As a direct and proximate result of the defective design of Zantac manufactured by Defendants and consumed by Plaintiff-decedent, Plaintiff suffered damages, including but not

limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future. Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

153. 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 AND GROSS NEGLIGENCE

154. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

155. Defendants had a duty to exercise ordinary and reasonable care in the design, manufacture, testing, sale, labeling, and/or distribution of Zantac it placed into the stream of commerce, including a duty to assure that the product did not cause foreseeable and unreasonable injury.

156. The Defendants have a duty to monitor the adverse effects associated with their pharmaceutical products, including Zantac.

157. The Defendants have a continuing duty to warn of the adverse effects associated with their pharmaceutical products, including Zantac, to avoid reasonably foreseeable risks.

158. The Defendants owed these duties to Plaintiff because it was foreseeable to each Defendant that consumers like Plaintiff would ingest and consequently be endangered by Zantac.

159. The Defendants knew that Zantac was likely to form NDMA within the human body in high quantities due to the inherent instability of the ranitidine molecule, and as a result of such NDMA formation, Zantac users would be exposed to unreasonable risks of cancer. The Defendants'

knowledge that NDMA would be formed within the human body as a result of Zantac usage, only grew with each year Zantac was on the market.

160. Defendants breached their duty of care to Plaintiff through its negligent acts and omissions. Defendants did not exercise reasonable care in the warning, design, manufacture, sale, testing, labeling, monitoring, and/or distribution into the stream of commerce of Zantac in that Defendants knew or should have known that Zantac could cause cancer when taken as directed.

161. The Defendants knew that the ranitidine molecule would likely break down into NDMA and other harmful metabolites in the body before Zantac was first approved by the FDA. Despite knowing that Zantac would cause these dangers in humans, the Defendants nonetheless proceeded with the design of the ranitidine molecule into Zantac.

162. Based, among other things, on their duty to monitor the adverse effects associated with Zantac, the Defendants knew that the likelihood and severity of the harm associated with Zantac usage was great. At least thousands of patients who took Zantac, including Plaintiff, experienced cancers proximately caused by Zantac use or have been exposed to an unreasonable risk of developing cancer. The likelihood and severity of the cancers suffered by Plaintiff and other users of Zantac far outweighed the Defendants' burden in taking safety measures to reduce or avoid the harm.

163. Defendants were negligent in the design, manufacture, sale, testing, and/or distribution of Zantac in that they: (a) failed to use due care in designing, formulating, developing, testing, manufacture, and sale of Zantac so as to avoid or warn against the described risks to consumers who used Zantac; (b) placed an unsafe product into the stream of commerce; and (c) failed to discover or warn of the dangers associated with the use of Zantac despite having actual and/or constructive knowledge of such dangers.

164. The Defendants knew or reasonably should have known that Zantac was dangerous or likely to be dangerous when used in a reasonably foreseeable manner.

165. Defendants knew or should have known that Plaintiffs could foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care as described above.

166. The Defendants failed to exercise ordinary care in the design, manufacture, and sale of Zantac.

167. The Defendants failed to use the amount of care in designing Zantac that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm.

168. The Defendants failed to use the amount of care in warning about the risks and safe use of Zantac that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm.

169. The Defendants knew or reasonably should have known that Plaintiff and Plaintiffs' physicians would not realize the danger posed by Zantac.

170. A reasonable manufacturer and seller under the same or similar circumstances would have instructed Plaintiffs and Plaintiff's physicians on the safe use of Zantac.

171. Defendants' failure to adequately warn Plaintiff and Plaintiff's doctors about the dangers of Zantac was compounded by the Defendants' omissions to doctors during sales and other promotional activities.

172. Plaintiff was injured by using Zantac in a reasonably foreseeable way.

173. The lack of adequate warnings was a substantial factor in causing Plaintiff's injuries.

174. Had the Defendants adequately warned Plaintiff, Plaintiff would have read and heeded such warnings, and Plaintiff would not have ultimately ingested Zantac.

175. Plaintiffs were injured as a direct and proximate result of the Defendants' negligence.

176. The Defendants' conduct constitutes gross negligence and willful misconduct.

177. By designing Zantac such that it formed NDMA and other harmful metabolites in the human body following ingestion, when they knew that Zantac acted this way and knew about the harmful effects of NDMA, 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.

178. The Defendants intentionally designed Zantac 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.

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

180. Each of the foregoing acts or omissions by Defendants, when viewed objectively from its standpoint at the time, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiffs and others.

181. Defendants acted with conscious indifference to the right, safety, or welfare of Plaintiffs and others. Their deceptive and inadequate labeling and marketing, misrepresentation of the risks of Zantac to doctors and the general public, and refusal to engage in proper safety evaluation and investigation both before and after Zantac was first sold, were undertaken in the callous pursuit of market advantage and without regard for the safety of those exposed to Zantac.

182. 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 WARRANTY

183. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

184. Defendants were merchants and sellers with respect to Zantac.

185. In order to induce the purchase and/or use of Zantac, Defendants expressly warranted to potential users of Zantac that Zantac was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used. Express warranties were contained in direct to consumer advertising and other promotional and marketing campaigns, Zantac product information sheets given to patients with their prescriptions, the product labeling, and other public communications and representations.

186. Defendants breached said warranty in that Zantac was not safe to be used for the purposes for which it was manufactured and/or advertised.

187. Plaintiffs were inured as a result of detrimental reliance upon Defendants' express warranties.

188. 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 WARRANTY

189. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

190. Defendants were manufacturers and merchant sellers with respect to Zantac.

191. An implied warranty of fitness for human consumption runs from each Defendant to consumers like Plaintiff.

192. In order to induce the purchase and/or use of Zantac, Defendants impliedly warranted to potential users of Zantac that Zantac was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used.

193. Defendants breached this warranty in that Zantac was not safe for the uses for which it was manufactured and/or advertised.

194. Plaintiff ingested Zantac for the treatment of acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease, which are the purposes for which the drugs were manufactured, sold, and prescribed.

195. Plaintiff relied on the Defendants' skill or judgment to provide a product suitable for this purpose. The Defendants are in the business of designing, manufacturing, selling, and marketing prescription drugs and specialize in drugs for the treatment or prevention of acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.

196. The Defendants had reason to know that Plaintiff and/or his doctors would rely on the Defendants' skill or judgment.

197. Zantac is unfit for the purpose for which it was purchased; it is toxic to patients when put to its intended and ordinary use, causing injuries to consumers.

198. 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 and other harmful metabolites in the body when ingested, something the Defendants knew or should have known.

199. Plaintiff suffered cancer and/or injuries as a result of detrimental reliance upon

Defendants' implied warranties and ingesting Zantac.

200. In addition to the common law, the conduct alleged herein constitutes a breach of the implied warranty of merchantability.

201. 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 VI: NEGLIGENT MISREPRESENTATION AND FRAUD

202. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

203. Defendants manufactured, designed, marketed, labeled, distributed, and sold Zantac.

204. Defendants have a duty not to deceive consumers and their physicians, including Plaintiff-decedent, about Zantac.

205. Defendants had a duty to disclose to Plaintiff-decedent, his physicians, and the public that Zantac was not safe for use by Plaintiff due to its carcinogenic effect.

206. Defendants made representations to Plaintiff-decedent and his physicians regarding the character and/or quality of Zantac for guidance in their decision to select Zantac for Plaintiff's use.

207. Specifically, Defendants represented that Zantac was just as safe as or even safer than other drugs for treatment of gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease available on the market.

208. Defendants knew, or should have known, that such statements were false.

209. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's physicians, and the healthcare industry the safety and effectiveness of Zantac and/or recklessly

and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Zantac.

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

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

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

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

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

e. that harmful levels of NDMA is carcinogenic;

f. the inadequacy of the labeling for Zantac; and

g. the dangerous carcinogenic effects of Zantac.

211. Defendants negligently and/or intentionally misrepresented this information in Zantac's labeling, promotions and advertisements, in order to avoid losses and sustain profits in their sales to consumers and instead labeled, promoted, and advertised their product as just as safe and effective as other H2 blockers.

212. In supplying this false information, Defendants failed to exercise reasonable care or competence in obtaining safety information concerning Zantac and in communicating this information to the intended recipients, including Plaintiff-decedent and his physicians. Further, Defendants were aware that without such safety information, it could not accurately make the above

described representations. Defendants knew about Zantac's relative risks and the true extent of its risks but chose to include false and misleading representations regarding those risks in its labeling, with the intent that Plaintiff and his doctors rely on them. Plaintiff did reasonably rely on those false and misleading representations in taking Zantac, which proximately caused harm to Plaintiff.

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

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

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

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

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

218. Plaintiff-decedent reasonably relied to his detriment upon Defendants' representations that Zantac was just as safe and effective as other methods of treating and

preventing gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.

219. Plaintiff-decedent reasonably relied to his detriment upon Defendants' representations that Defendants' labeling, advertisements and promotions fully and accurately described all known risks of the product.

220. Had Plaintiff-decedent or his physician known of Defendants' concealment of the true facts – that Zantac was more dangerous than other H2 blockers, Plaintiff-decedent would not have ingested Zantac.

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

222. As a direct and proximate result of the foregoing concealments and omissions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

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

224. 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 VII: WRONGFUL DEATH

225. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

226. As a result of the foregoing, on January 12, 2018, Plaintiff-decedent, Richard O'Neal died from complications proximately related to the Defendant's Zantac.

227. Plaintiff-decedent, Richard O'Neal, left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedent's death have suffered a pecuniary and/or non-pecuniary loss including, but not limited to support, income, services and guidance of the Plaintiff-decedent, Richard O'Neal, and were all permanently damaged thereby.

228. At all times herein mentioned, the actions of the named Defendants and their agents, servants, and/or employees, were wanton, grossly negligent, reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the general public and to the decedent in particular.

COUNT VIII: PUNITIVE DAMAGES

229. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

230. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages.

231. As a direct and proximate result of Defendants' malicious, fraudulent, and/or intentional disregard of Plaintiffs' rights, Plaintiff is entitled to punitive damages to punish Defendants and deter similar wrongdoing by others in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against all Defendants as follows:

1. For economic and non-economic damages, special damages, and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;

2. For actual or compensatory damages for the acts complained of herein in an amount to be determined by a jury and as provided by applicable law;

3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. For exemplary and punitive damages sufficient to punish Defendants for the acts complained of herein and to deter Defendants and others from future wrongful practices, in an amount to be determined by a jury;

5. For an award of reasonable attorneys' fees, court costs, and other litigation expenses;

6. For prejudgment interest;

7. For post-judgment interest; and

8. For such other and further relief as this Court may deem just and proper.

Dated: January 10, 2020

Respectfully submitted,

By: /s/ Morris Dweck

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: January 10, 2020

Respectfully submitted,

By: /s/ Morris Dweck

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