UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

John Scholl, Ryan Dahl, Brad Hoag, on behalf of themselves and all others similarly situated, Plaintiffs, v. Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; Chattem, Inc.; and Boehringer Ingelheim Pharmaceuticals, Inc., Defendants.	Case No. _____ **CONSOLIDATED CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs bring this action on behalf of themselves and all others similarly situated and file this consolidated class action complaint against Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; Chattem, Inc.; and Boehringer Ingelheim Pharmaceuticals, Inc. Plaintiffs allege the following based on information and belief, the investigation of counsel, and personal knowledge as to the allegations pertaining to themselves.

I. INTRODUCTION

1. Zantac—the brand-name version of the generic drug ranitidine—is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease. Zantac was first sold in the United States in 1983; three years later, it became the first drug to total $1 billion in sales.

2. As recently as 2018, Zantac was widely used and remained one of the most popular tablet brands of antacid in the United States, with sales of Zantac 150 (the over-

the-counter tablets containing a 150 mg dose) totaling $128.9 million annually. Over-the-counter Zantac also is sold in the form of tablets containing a 75 mg dose (Zantac 75).

3. But Zantac's unprecedented sales were possible only because of a deception perpetrated by the drug's manufacturers on consumers who have purchased Zantac since it hit the market in 1983. Sanofi and Boehringer are only the most recent perpetrators of this deception. These companies never disclosed to consumers that the drug has a critical defect. If ingested, Zantac produces high quantities of N-Nitrosodimethylamine (NDMA) in the human body. NDMA is a chemical that the World Health Organization has described as "clearly carcinogenic." The dangers of NDMA have been publicly known for over 40 years. NDMA itself belongs to a family of chemicals called N-nitrosamines, which the U.S. Environmental Protection Agency refers to as "potent carcinogens."

4. Recent scientific testing conducted by Valisure LLC and ValisureRX LLC (collectively "Valisure") "has detected extremely high levels of NDMA in *all lots [of ranitidine] tested*, across multiple manufacturers of ranitidine products," including Zantac.

5. Valisure has notified the FDA of its findings by filing a citizen petition on September 13, 2019.

6. Valisure is an "online pharmacy currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization." Valisure also is registered with the Drug Enforcement Administration

and the FDA. The tests conducted by Valisure show that "ranitidine can react with itself in standard analysis conditions. . . at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen." The FDA recently announced a permissible intake limit of 96 ng of NDMA per day. These low limits are consistent with the public health statement issued 30 years ago by the Agency for Toxic Substances and Disease Registry, which warned of the dangers posed by NDMA, noting among other things that "high level short-term and low level long-term exposures [to NDMA] caused non-cancerous liver damage and/or cancer in animals [and] also usually resulted in internal bleeding and death."

7. Valisure's testing—which employs the FDA's own gas chromatography/mass spectrometry ("GC/MS") protocol—detects 2,511,469 ng of NDMA per 150 mg tablet of Zantac. The FDA-recommended protocol detects a quantity of NDMA in each Zantac tablet that is more than 26,000 times greater than the amount that can be safely ingested daily.

8. "The typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily."[1] Moreover, chronic use of the drug is common "for therapy of heartburn and indigestion."

9. Thus, a typical consumer who is taking Zantac over the course of eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28

[1] *Drug Record: Ranitidine*, NATIONAL INSTITUTES OF HEALTH (updated July 1, 2019), https://livertox.nih.gov/Ranitidine.htm.

grams) of NDMA. And a consumer who takes a 150 mg maintenance dose of Zantac once daily is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year. Again, the FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year.

10. Zantac is used not only by adults but is also given to children and teenagers to treat gastroesophageal reflux, among other things.

11. In addition to the FDA-recommended testing described above, when Zantac was tested "in conditions simulating the human stomach," the quantity of NDMA detected was as high as 304,500 ng per tablet—3,171 times more than the amount that can be safely ingested daily. Recent peer-reviewed scientific literature has demonstrated the existence of dangerous levels of NDMA in the urine of those who have taken ranitidine.

12. Sanofi has owned the U.S. rights to over-the-counter Zantac since about January 2017 and has manufactured and distributed the drug during that period. Previously, Defendant Boehringer owned the U.S. rights to Zantac and manufactured and distributed the drug from about October 2006 to January 2017.

13. Both Sanofi and Boehringer knew or had reason to know that Zantac exposes users to unsafe levels of the carcinogen NDMA: During the period that Sanofi and Boehringer manufactured and distributed Zantac, numerous scientific studies were published showing, among other things, that ranitidine (the generic bioequivalent of Zantac) forms NDMA when placed in drinking water and that a person who consumes ranitidine has a 400-fold increase of NDMA concentration in their urine.

14. Despite the weight of scientific evidence showing that Zantac exposed users to unsafe levels of the carcinogen NDMA, neither Sanofi nor Boehringer disclosed this risk to consumers on the drug's label—or through any other means. Had Defendants disclosed that Zantac results in unsafe levels of NDMA in the human body, no person, let alone a reasonable person, would have purchased and consumed Zantac.

15. Plaintiffs are persons who have previously purchased the over-the-counter version of the drug Zantac. In this suit, Plaintiffs seek to represent a Class of those persons who purchased over-the-counter Zantac in the State of Minnesota between January 1, 2010 and the present.

16. Had Plaintiffs and the Class known that taking Zantac would expose them to high levels of the carcinogen NDMA, they would not have purchased the drug.

17. Defendants' failure to disclose this material information to Plaintiffs and the Class violates Minnesota's consumer-protection laws.

II. PARTIES

18. Plaintiff John "Bucky" Scholl is a resident of Alexandria, Minnesota in Douglas County. Mr. Scholl purchased over the counter Zantac, at least as early as 2010, and subsequently took the drug. If Mr. Scholl had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased the drug.

19. Plaintiff Ryan Dahl is a resident of Chanhassen, Minnesota in Carver County. Mr. Dahl purchased over the counter Zantac, at least as early as September 2017, and subsequently took the drug. If Mr. Dahl had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased the drug.

20. Plaintiff Brad Hoag is a resident of Plymouth, Minnesota in Hennepin County. Mr. Hoag purchased over the counter Zantac, at least as early as 2014, and subsequently took the drug. If Mr. Hoag had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased the drug.

21. 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.

22. 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.

23. 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.

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

25. 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 Zantac from about October

2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

III. JURISDICTION AND VENUE

26. This Court has jurisdiction under 28 U.S.C. § 1332(d), which provides federal district courts with original jurisdiction over any civil action in which the matter in controversy exceeds the sum or value of $5 million, exclusive of interests and costs, and is a class action in which any member of a class of plaintiffs is a citizen of a state different from any defendant.

27. The Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District. Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

28. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) because each Defendant transacts business in, is found in, and/or has agents in the District of Minnesota, and because some of the actions giving rise to this complaint took place within this district.

IV. FACTUAL ALLEGATIONS

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

30. Due in large part to Glaxo'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." Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[2]

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

32. Over the past 20 years, the rights to Zantac in the U.S. have changed hands several times.

33. As relevant here, Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006, and manufactured and sold the drug in the United States—including in Minnesota—from approximately January 2007 to January 2017.

34. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and have since been manufacturing and selling the drug in the United States, including in Minnesota.

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[2] Richard Wright, M.D., How Zantac Became the Best-Selling Drug in History, 16(4) J. OF HEALTHCARE MARKETING 24, 27 n.2 (Winter 1996).

A. The Dangers of N-Nitrosodimethylamine (NDMA)

35. "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[3]

36. 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."[4] NDMA is no longer produced or commercially used in the United States, except for research. In other words, it is only a poison.

37. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen. And the World Health Organization has stated that scientific testing indicates that "NDMA consumption is

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[3] *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)*, ENVIRONMENTAL PROTECTION AGENCY (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[4] 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").

positively associated with either gastric or colorectal cancer" and "suggests that humans may be especially sensitive to the carcinogenicity of NDMA."[5]

38. 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.

39. 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," which provide that the intake of NDMA should be no more than 96 ng. 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.

40. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets.

41. Applying the FDA-recommended GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan—the level of

[5] *Technical Fact Sheet*, *supra* footnote 39; 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.

NDMA in Zantac is 2,511,469 ng per Zantac tablet—124 times more than the highest amount detected in the recalled valsartan.

42. Moreover, the high levels of NDMA produced by Zantac 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." Thus, ranitidine produces NDMA by "react[ing] with itself," which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.

43. Defendants did not disclose to consumers that Zantac exposes users to high levels of the carcinogen NDMA, despite scientific studies alerting defendants of this fact.

44. 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. Neither Sanofi nor Boehringer disclosed this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA.

45. Although there were some scientific articles linking ranitidine—the active ingredient in Zantac—to NDMA in the first few years after the drug's U.S. launch, those articles tended to minimize the danger that ranitidine posed to consumers.

46. During the time that Defendants were manufacturing and selling over-the-counter Zantac in the United States, however, the scientific evidence linking Zantac and NDMA was mounting and could no longer be ignored.

47. 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. The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature." Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."

48. 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 precursors."

49. 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." 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." The article also cautioned that these "estimates are conservative" and the actual exposure to NDMA is "likely much higher than that eliminated in urine" since NDMA has "a high metabolic conversion rate" so only about 0.05% of NDMA in the body is excreted in urine. 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." 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."

50. A 2018 scientific review "summariz[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)" again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."

51. 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.

52. 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.

53. 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 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."

54. 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."

55. 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.

56. 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.

V. CLASS ACTION ALLEGATIONS

57. Plaintiffs bring this action under Federal Rule of Civil Procedure 23(a) and (b)(3), on behalf of themselves and the members of the following Class during the period of January 1, 2010 through the present ("Class Period"):

> All individual residents of Minnesota who purchased over-the-counter Zantac for personal, family, or household use during the Class Period.

58. Excluded from the Class are each Defendant and any entity in which a Defendant has a controlling interest, as well as any Defendant's legal representatives, officers, directors, assignees, and successors.

59. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. During the Class Period, over-the-counter Zantac was one of the best-selling antacid medications in the United States. Hundreds of

thousands—if not millions—of persons purchased the drug. Class members are readily identifiable from information and records in the possession of Defendants and third-party pharmacies such as CVS, Walgreens, Walmart, and Rite Aid.

60. Plaintiffs' claims are typical of the claims of the members of the class. Plaintiffs and all Class members were damaged by the same wrongful conduct of Defendants: As a result of Defendants' failing to disclose that Zantac exposed users to unsafe levels of the carcinogen NDMA, Plaintiffs and the other Class members were misled into purchasing Zantac—a drug they otherwise would not have purchased. There are numerous Zantac substitutes; in addition to other H2 blockers such as Pepcid-AC and Tagamet-HB, there are also proton pump inhibitors—for example, Dexilant, Nexium, Prevacid, Protonix, AcipHex, and Prilosec—which "block the enzyme in the stomach wall that makes acid."

61. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other members of the Class.

62. Plaintiffs' counsel are experienced in the prosecution of class-action litigation and have particular experience with class-action litigation involving pharmaceutical products.

63. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby

making damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful actions.

64. Questions of law and fact common to the Class include, but are not limited to:

a. Whether the Zantac sold by Defendants exposed Plaintiffs and the other Class members to unsafe levels of the carcinogen NDMA;

b. Whether Defendants knew or had reason to know that Zantac exposes users to unsafe quantities of NDMA;

c. Whether Defendants acted to conceal from consumers that Zantac exposes users to unsafe quantities of NDMA;

d. Whether Defendants' conduct was knowing or willful;

e. Whether Defendants notified the FDA that Zantac exposes users to unsafe quantities of NDMA;

f. Whether Defendants attempted to gain approval from the FDA to change Zantac's label to add a warning that the drug exposes users to unsafe quantities of NDMA;

g. Whether Defendants acted to conceal from the FDA the link between Zantac and NDMA;

h. Whether Defendants' failure to disclose on Zantac's label (or elsewhere) that the drug produces high levels of the carcinogen NDMA was unfair, deceptive, fraudulent, or unconscionable;

i. Whether Defendants are liable to Plaintiffs and the other Class members for damages under state consumer-protection statutes;

j. When Defendants manufactured and sold Zantac in the United States;

k. Whether an injunction should be issued requiring Sanofi Defendants to disclose on Zantac labels that the drug exposes users to unsafe levels of NDMA; and

l. Whether Plaintiffs and the other Class members are entitled to attorneys' fees, prejudgment interest, and costs, and if so, in what amount.

65. Plaintiffs and the other Class members have all suffered harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism—including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually—substantially outweigh potential difficulties in management of this class action. Absent a class action, most members of the class would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The class treatment of common questions of law and fact also is superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of

adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

VI. TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Tolling

66. Plaintiffs and the class members had no realistic opportunity to know that Defendants were not disclosing the high levels of the carcinogen NDMA produced by Zantac. In addition, despite their due diligence, Plaintiffs and the Class could not reasonably have expected to learn or discover that Defendants concealed material information about Zantac.

67. Plaintiffs and the other Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants did not disclose the high levels of NDMA produced by Zantac. The information linking Zantac to NDMA was contained exclusively in scholarly articles that were published in scientific journals not widely available to Plaintiffs and the other Class members.

68. Plaintiffs and the other Class members could not have reasonably discovered the true extent of Defendants' deception with regard to Zantac's safety until Valisure filed its citizen petition disclosing the extremely high levels of NDMA produced by Zantac.

69. Defendant's knowledge and active concealment of the high levels of NDMA has tolled any applicable statute of limitation. Defendants are estopped from

relying on any statute of limitation because the company concealed knowledge about Zantac's true characteristics.

70. Because Plaintiffs and the class members could not have reasonably known about the factual basis for their claims, and because Defendants continued to manufacture and sell Zantac without disclosing this information on the drug's label or elsewhere, plaintiffs' claims should be tolled.

B. Estoppel

71. Defendants were under a continuous duty to disclose to Plaintiffs and the other Class members the risk of NDMA exposure associated with Zantac.

72. 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.

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

VII. CAUSES OF ACTION

COUNT I
Violation the Minnesota Prevention of Consumer Fraud Act
(Minn. Stat.§§ 325F.68, et seq.)

74. Plaintiffs re-allege and incorporate by reference all the above allegations as if fully set forth herein. Plaintiffs bring this claim on behalf of themselves the Minnesota Class.

75. The Minnesota Prevention of Consumer Fraud Act ("Minnesota CFA") prohibits "[t]he act, use, or employment by any person of any fraud, false pretense, false

promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." Minn. Stat. § 325F.69 subd. 1.

76. Defendants participated in misleading, false, or deceptive acts that violated the Minnesota CFA.

77. Zantac constitutes "merchandise" within the meaning of Minn. Stat. § 325F.68 subd. 2.

78. Defendants constitute a person within the meaning of Minn. Stat. § 325F.68, subd. 3.

79. In the course of their business, Defendants concealed and suppressed material facts concerning Zantac. As alleged in this Complaint:

a. Defendants' failure to disclose—by labeling or otherwise—the NDMA risk presented by Zantac constitutes "deceptive" acts in violation of the Minnesota CFA. Defendants' conduct constituted misleading, false, unfair or deceptive acts or practices that violated the Minnesota CFA.

b. In purchasing Zantac from Defendants, Plaintiffs and the other Class members were deceived by Defendants' failure to disclose that Zantac exposes consumers to high levels of the carcinogen NDMA.

80. Defendants' deceptive acts or practices were likely to and did in fact deceive Plaintiffs and the Class about the true characteristics of Zantac, including the high rate of NDMA.

81. Plaintiffs and the Class actually relied on Defendants' misrepresentations and omissions alleged herein, which led Plaintiffs and Class to believe that.

82. Absent those misrepresentations and omissions, Plaintiffs and the Class would not have purchased the products, would not have purchased the products at the prices they paid, and/or would have purchased less expensive alternative over-the-counter medications.

83. Plaintiffs and the Class suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' misrepresentations about the characteristics of Zantac.

84. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

85. Defendants' unlawful acts and practices complained of herein affect the public interest. As a direct and proximate result of Defendants' violations of the Minnesota CFA, Plaintiffs and the Class have suffered injury-in-fact and/or actual damage. Pursuant to Minn. Stat. § 8.31 subd. 3a, Plaintiffs and the Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota CFA.

86. Defendants knew or should have known that their conduct violated the Minnesota CFA.

87. Plaintiffs and the Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota CFA. This action will achieve a public benefit. The misrepresentations by Defendant were significant and directly

contributed to the harm suffered by Plaintiffs. The misrepresentations were made to increase profits at the expense of Plaintiffs and its patients. Plaintiffs seek monetary and injunctive relief, in order to stop further damage to Zantac consumers throughout the country.

88. In the alternative, pursuant to Minn. Stat. §§ 325F.69 subd. 1 and 325F.70 subd. 1, Plaintiffs request that this Court enjoin Defendant from engaging in the methods, acts, or practices alleged herein, and requiring Defendants to either (i) cease selling Zantac or (ii) add a label to their Zantac packaging warning consumers of the high levels of NDMA they will be exposed to by taking the drug

COUNT II
Violation of Minnesota Uniform Deceptive Trade Practices Act
(Minn. Stat. §§ 325D.43-48, et seq.)

89. Plaintiffs re-allege and incorporate by reference all the above allegations as if fully set forth herein. Plaintiffs bring this claim on behalf of themselves and the Minnesota Class.

90. The Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.44, ("Minnesota DTPA") prohibits, *inter alia*, deceptive trade practices, which occur when a person "(5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;" and "(7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

91. In the course of Defendants business, it engaged in deceptive practices by representing that Zantac had characteristics, ingredients, uses, benefits, or qualities that it does not have; representing that Zantac was of a particular standard, quality, or grade.

92. In the course of their business, Defendants concealed and suppressed material facts concerning Zantac. As alleged in this Complaint:

a. Defendants' failure to disclose—by labeling or otherwise—the NDMA risk presented by Zantac constitutes deceptive acts in violation of the Minnesota DTPA. Defendants' conduct constituted misleading, false, unfair or deceptive acts or practices that violated the Minnesota DTPA.

b. In purchasing Zantac from Defendants, Plaintiffs and the other Class members were deceived by Defendants' failure to disclose that Zantac exposes consumers to high levels of the carcinogen NDMA.

c. Defendants' failure to disclose to Plaintiffs and Class members the NDMA levels present in Zantac is likely to deceive members of the public into believing that the drug would not expose them to the known carcinogen NDMA.

93. Defendants participated in misleading, false, or deceptive acts that violated the Minnesota DTPA. By failing to disclose and by actively concealing the fact that Zantac had high levels of NDMA, Defendants engaged in deceptive business practices prohibited under the Minnesota DTPA. Defendants' actions as set forth above occurred in the conduct of trade or commerce.

94. In the course of its business, Defendants willfully failed to disclose and actively concealed the high carcinogen levels in Zantac. Defendants also engaged in deceptive trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of Zantac.

95. Defendants knew the true nature of Zantac, and the potential harm plaintiffs and member of the class could experience.

96. Defendants intentionally and knowingly misrepresented material facts regarding Zantac with the intent to mislead Plaintiffs and the Class.

97. Defendants knew or should have known that its conduct violated the Minnesota DTPA. And Defendants unfair or deceptive acts or practices were likely to and did in fact deceive Plaintiffs and the Class about the true characteristics and value of Zantac.

98. Plaintiffs and the Class actually relied on Defendants' misrepresentations and omissions alleged herein, which led Plaintiffs and members of the Class to believe that Zantac was safe.

99. Absent those misrepresentations and omissions, Plaintiffs and the Class would not have purchased the products, would not have purchased the products at the prices they paid, and/or would have purchased alternative antacid medications that did not contain the carcinogen NDMA.

100. Plaintiffs and the Class suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' misrepresentations and its concealment of and failure to disclose material information about Zantac. Plaintiffs and the Class who purchased Zantac would not have purchased Zantac if the products' true nature had been disclosed, or would have paid significantly less for it, which shows that Plaintiffs and the Class actually relied on Defendants' misrepresentations and omissions.

101. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

102. Pursuant to Minn. Stat. § 8.31 subd. 3a, Plaintiffs and the Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota DTPA. This action will achieve a public benefit. The misrepresentations by Defendants were significant, directed to millions of consumers, and directly contributed to the harm suffered by Plaintiffs and the Class. The misrepresentations were made to increase profits at the expense of Plaintiffs. Plaintiffs and the Class seek monetary and injunctive relief, in order to stop further damage to antacid consumers throughout the country.

103. In the alternative, pursuant to Minn. Stat. § 325D.45, Plaintiffs and the Class are likely to be harmed going forward by the sale and distribution of Zantac. As such, Plaintiff seek injunctive relief requiring Defendants to cease the complained of methods, acts, or practices, and requiring Defendants to either (i) cease selling Zantac or (ii) add a label to their Zantac packaging warning consumers of the high levels of NDMA they will be exposed to by taking the drug

104. Defendants willfully engaged in deceptive trade practices in violation of the DTPA, and as a result, Plaintiffs and the Class are entitled to costs and attorneys' fees.

COUNT III
Violation of Minnesota Unlawful Trade Practices Act
(Minn. Stat. § 325D.09, *et seq.*)

105. Plaintiffs re-allege and incorporate by reference all the above allegations as if fully set forth herein. Plaintiffs bring this claim on behalf of themselves and the Class.

106. The Minnesota Unlawful Trade Practices Act (Minnesota UTPA), Minn. § 325D.13, states that "No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise."

107. In the course of their business, Defendants concealed and suppressed material facts concerning the true quality of Zantac. Defendants did this by failing to disclose the high levels of NDMA in Zantac, and the potential harm to consumers if ingested. Plaintiffs and the Class had no way of discerning that Defendants' representations about Zantac were false and misleading. Defendants' conduct constituted misleading, false, unfair or deceptive acts or practices that violated the Minnesota UTPA. Defendants knew or should have known that its conduct violated the Minnesota UTPA, and Defendants owed a duty Plaintiffs and the Class.

108. Defendants' unlawful acts or practices were likely to and did in fact deceive Plaintiffs and the Class about the true quality of Zantac. Plaintiffs and the Class actually relied on Defendants' misrepresentations and omissions alleged herein, which led Plaintiffs and Class to believe that Zantac did not contain dangerous carcinogens.

109. Absent those misrepresentations and omissions, Plaintiffs and the Class would not have purchased the products, would not have purchased the products at the prices they paid, and/or would have purchased less expensive alternative over-the-counter medication.

110. The facts concealed and omitted by Defendants from Plaintiffs and the other Class members are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase over-the-counter Zantac. Had Plaintiffs and the other Class members known about the defective nature of Zantac, they would not have purchased Zantac and instead would have purchased one of many available substitute medications.

111. Accordingly, Plaintiffs and the other Class members have suffered injury-in-fact, including lost money or property, as a result of Defendants' misrepresentations and omissions.

112. Plaintiffs' and the other Class members' injuries were proximately caused by Defendants' unlawful and deceptive business practices.

113. Pursuant to Minn. § 8.31(3a), Plaintiffs and the Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota UTPA. This action will achieve a public benefit. The misrepresentations by Defendants were significant, directed to millions of consumers, and directly contributed to the harm suffered by Plaintiffs and the Class. The misrepresentations were made to increase profits at the expense of Plaintiffs. Plaintiffs and the Class seek monetary and injunctive relief, in order to stop further damage to the class.

114. Additionally, pursuant to Minn. § 325D.15, Plaintiffs and the Class have been harmed and are likely to be harmed going forward by the sale and distribution of Zantac, and are entitled to actual damages, as well as injunctive relief. As such, Plaintiffs request that this Court enter such orders or judgments as may be appropriate, including a declaratory judgment that each Defendant has violated the Minnesota UTPA and enjoining Defendants from continuing their unfair, unlawful, and/or fraudulent trade practices.

COUNT IV
Unjust Enrichment

115. Plaintiffs re-allege and incorporate by reference all the above allegations as if fully set forth herein. Plaintiffs bring this claim on behalf of themselves and the Class.

116. Defendants have benefitted from selling Zantac, whose value was artificially inflated by Defendants' concealment of the high levels of NDMA in Zantac, and the potential harm to consumers if ingested. Accordingly, Defendants have been unjustly enriched at the expense of Plaintiffs and the Class.

117. Defendants have received and retained unjust benefits from the Plaintiffs and Class, and an inequity has resulted.

118. It is inequitable and unconscionable for Defendants to retain these benefits. Because Defendants concealed its fraud and deception, Plaintiffs and the Class were not aware of the true facts concerning Zantac and certainly did not benefit from Defendants' misconduct.

119. Defendants knowingly accepted the unjust benefits of its fraudulent conduct and other misconduct.

120. As a result of Defendants' misconduct, the amount of its unjust enrichment should be disgorged and returned to Plaintiffs and the Class in an amount to be proven at trial.

COUNT V
Negligence

121. Plaintiffs re-allege and incorporate by reference all the above allegations as if fully set forth herein. Plaintiffs bring this claim on behalf of themselves and the Class.

122. Plaintiff brings this cause of action individually and on behalf of the Class.

123. With respect to its testing, producing, marketing, and selling Zantac, Defendants had a duty to use its professional expertise and exercise the degree of skill and learning ordinarily used under the same, or similar, circumstances by a person or entity in Defendants' business.

124. Defendants breached this duty by failing to exercise the requisite degree of care in testing, producing, marketing, and selling Zantac to prevent it from harming users.

125. As a result, the Plaintiffs and other class members were harmed.

126. The damages incurred by Plaintiffs and the other Class members were, or should have been, foreseen by Defendants, as Defendants were uniquely positioned to understand the risks of Zantac.

127. Defendants breached its duties, as alleged above, and breached the requisite standard of care owed to all foreseeable plaintiffs and were therefore negligent.

128. Defendants' breaches were a direct and proximate cause of the injuries and damages sustained by the Plaintiff and the other Class members.

129. As a direct and proximate result of the foregoing, Plaintiff and the Class have been injured and suffered financial loss for which damages, injunctive, declaratory and other relief as may be available at law or equity is warranted.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request on behalf of themselves and members of the Class that the Court enter an order or judgment against Defendants including the following:

A. An order determining this action may be maintained as a class action under Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to members of the Class;

B. An order designating Plaintiffs as representatives of the Class and appointing their counsel as Class Counsel;

C. Judgment temporarily and permanently enjoining Defendants from continuing the unlawful, deceptive, fraudulent, harmful and unfair business conduct and practices alleged in this complaint;

D. Judgment temporarily and permanently enjoining Defendants from continuing to sell, market or distribute Zantac;

E. Judgment against Defendants in favor of Plaintiffs and the class members;

F. Any and all applicable statutory and civil penalties;

G. An order requiring Defendants to pay both pre- and post-judgment interest on any amounts awarded;

H. An award of costs and attorneys' fees, as allowed by law;

I. Leave to amend this Complaint to conform to the evidence; and

J. Such other or further relief as the Court may deem appropriate, just, and equitable.

IX. DEMAND FOR JURY TRIAL

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

Dated: December 6, 2019

Respectfully submitted,

s/Amanda M. Williams

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