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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARY SANTORELLA, MICHAEL BURKE, STEPHANIE HARRIS, RICHARD HARRIS, KASSIE BENSON, and LISA PRISINZANO, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; CHATTEM, INC.; and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Civil Action No. **COMPLAINT and** **DEMAND FOR JURY TRIAL**

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Plaintiffs, on behalf of themselves and all others similarly situated, in their action against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") allege the following based on personal knowledge, the investigation of counsel, and information and belief.

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.[1] 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]

2. As recently as 2018, Zantac was widely used and remained one of the most popular tablet brands of antacid[3] in the United States, with sales of Zantac 150 (the over-the-counter tablets containing a 150 mg dose) totaling $128.9 million annually.[4] Over-the-counter Zantac also is sold in the form of tablets containing a 75 mg dose (Zantac 75).

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[1] *Ranitidine hydrochloride – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE (last visited Sept. 19, 2019), https://www.pdr.net/drug-summary/Zantac-150-and-300-Tablets-ranitidine-hydrochloride-241.3325.

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

[3] Zantac is not technically an antacid because it "works by reducing the amount of acid [the] stomach makes," whereas antacids "neutralize the acid that your stomach has already made." *See Ranitidine, Oral Tablet*, HEALTHLINE (last visited Sept. 13, 2019), https://www.healthline.com/health/ranitidine-oral-tablet. Nonetheless, this Complaint sometimes refers to Zantac as an antacid because this is often how the drug is referred to colloquially. *See, e.g., Leading antacid tablet brands in the United States in 2018, based on sales*, STATISTA (last visited Sept. 13, 2019), https://www.statista.com/statistics/194544/leading-us-antacid-tablet-brands-in-2013-based-on-sales/.

[4] *Leading antacid tablet brands in the United States in 2018*, *supra* footnote 3.

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.

4. 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.

5. But neither Sanofi nor Boehringer ever disclosed to consumers that the drug has a critical defect: When ingested, Zantac produces in the human body high quantities of N-Nitrosodimethylamine (NDMA), a chemical that the World Health Organization has described as "clearly carcinogenic."[5] The dangers of NDMA have been publicly known for over 40 years.[6] NDMA itself belongs to a family of chemicals called N-nitrosamines, which the U.S. Environmental Protection Agency refers to as "potent carcinogens."

6. 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.[7]

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[5] R.G. Liteplo, et al., *Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine*, WORLD HEALTH ORGANIZATION (2002), *available at* https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

[6] *See, e.g.,* Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979) ("As one of a family of carcinogens called nitrosamines, NDMA has caused cancer in nearly every laboratory animal tested so far.").

[7] Valisure Citizen Petition to FDA ("Citizen Petition") at 6 (emphasis added), *available at* https://hbw.pharmaintelligence.informa.com/~/media/Supporting%20Documents/Rose%20Sheet/2019/09/9%20Sept%202019%20Valisure%20Ranitidine%20Petition.pdf.

7. Valisure has notified the FDA of its findings by filing a citizen petition on September 13, 2019.[8]

8. 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."[9] Valisure also is registered with the Drug Enforcement Administration and the FDA.[10] 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."[11]

9. The FDA recently announced a permissible intake limit of **96 ng** of NDMA per day.[12] But even this limit may be too high: A public health statement issued 30 years ago by the Agency for Toxic Substances and Disease Registry 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."[13]

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8 *Id.*

9 *Id.* at 2.

10 *Id.*

11 *Id.*

12 *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)*, FDA (last updated Aug. 28, 2019) (setting "interim limits for NDMA" and other nitrosamines at 96 ng/day for angiotensin II receptor blockers).

13 Agency for Toxic Substances & Disease Registry, *Public Health Statement for n-Nitrosodimethylamine* 2 (Dec. 1989) (emphasis added), available at https://www.atsdr.cdc.gov/ToxProfiles/tp141-c1-b.pdf. The public health statement also notes that "[s]hort-term or long-term exposure of animals to water or food containing NDMA is also

10. 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.[14] In other words, the FDA-recommended protocol detects a quantity of NDMA in each Zantac tablet that is more than **26,000 times** greater than the FDA's daily permissible intake levels.

11. "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."[15] Moreover, chronic use of the drug is common "for therapy of heartburn and indigestion."[16]

12. 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 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 for consumers who take a daily 150 mg maintenance dose.

13. Zantac is used not only by adults but is also given to children and teenagers to treat gastroesophageal reflux, among other things.[17]

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associated with serious effects, such as liver disease and death, at levels ranging from 5 to 50 ppm [parts per million] in water and 5 to 100 ppm in food." *Id.* at 3.

[14] Citizen Petition, *supra* footnote 7, at 6.

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

[16] *Id.*

[17] *Treatment for GER & GERD in Children & Teens*, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (Apr. 2015), https://www.niddk.nih.gov/health-information/digestive-diseases/acid-reflux-ger-gerd-children-teens/treatment.

14. In addition to the FDA-recommended testing described above, when Valisure tested Zantac "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.[18] This is consistent with recent peer-reviewed scientific literature, which has demonstrated the existence of dangerous levels of NDMA in the urine of those who have taken ranitidine.[19]

15. When the news broke on September 13, 2019 that Zantac exposed users to NDMA, "[g]lobal health regulators sounded a coordinated alarm."[20]

16. Some countries' regulators have taken steps to protect the public from exposure to ranitidine. 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."[21]

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[18] Citizen Petition, *supra* footnote 7, at 6–7.

[19] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of* N-*nitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).

[20] Anna Edney & John Lauerman, *Carcinogen in Zantac and its generics triggers probes by FDA, EU*, THE HAMILTON SPECTATOR (Sept. 13, 2019), https://www.thespec.com/news-story/9595764-carcinogen-in-zantac-and-its-generics-triggers-probes-by-fda-eu/.

[21] *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.

17. Germany, Switzerland, and Austria all have initiated recalls of ranitidine-based drugs,[22] and Finland has withdrawn drugs containing ranitidine from its pharmacies.[23] Singapore has suspended the sale and supply of several brands of ranitidine.[24] 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."[25]

18. Some companies that manufacture and distribute generic Zantac also have taken action to protect consumers. Sandoz, a unit of Novartis AG, has stopped its "worldwide distribution of generic versions" of Zantac.[26]

19. Unfortunately, the FDA has done very little to protect the American public with respect to Zantac. On September 13, 2019, the FDA issued a statement acknowledging that Zantac contains NDMA but, in a seeming attempt to downplay the issue, claimed that the amount of NDMA detected was low: "The U.S. Food and Drug Administration has learned that some

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

23 *Pharmacies pull heartburn meds over contamination concerns*, UUTISET (Sept. 19, 2019), https://yle.fi/uutiset/osasto/news/pharmacies_pull_heartburn_meds_over_contamination_concerns/10977530.

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

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

26 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.

ranitidine medicines, including some products commonly known as the brand-name drug Zantac, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels."[27] Further, although numerous regulators outside of the United States have cautioned those taking Zantac to consider taking an alternative medication given the availability of many safe alternative medicines, the FDA informed the American public that it need not discontinue taking OTC Zantac.[28]

20. Like the FDA, Sanofi—which currently manufactures and distributes over-the-counter Zantac in the United States—has taken no steps to protect the American public. Sanofi has announced that it "isn't halting distribution of the drug or any of its other ranitidine products outside of Canada."[29]

21. Both Sanofi and Boehringer (which manufactured over-the-counter Zantac from 2006 through 2016) 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

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[27] FDA, *Statement alerting patients and health care professionals of NDMA found in samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[28] *FDA to review ranitidine after detecting cancer-causing contamination*, PHARMACEUTICAL TECHNOLOGY (Sept. 16, 2019), https://www.pharmaceutical-technology.com/news/fda-ranitidine-review/.

[29] Anna Edney, *Carcinogen scare sets off global race to contain tainted Zantac*, LOS ANGELES TIMES (Sept. 18, 2019), *available at* https://www.latimes.com/business/story/2019-09-18/carcinogen-scare-tainted-zantac.

(the generic bioequivalent of Zantac) forms NDMA when placed in drinking water[30] and that a person who consumes ranitidine has a 400-fold increase of NDMA concentration in their urine.[31]

22. Despite the weight of scientific evidence showing that Zantac exposed users to unsafe levels of the carcinogen NDMA, neither Sanofi nor Boehringer ever 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.

23. Plaintiffs are persons who have previously purchased the over-the-counter version of the drug Zantac in either New Jersey, Florida, or Massachusetts between January 1, 2010 and the present (the "relevant period" or the "Class Period").

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

25. Defendants' failure to disclose this material information to Plaintiffs and Class members violates the laws of New Jersey, Florida, and Massachusetts.

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30 *See, e.g.*, Massimiliano Sgroi, et al., *N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal*, 191 CHEMOSPHERE 685 (Oct. 15, 2017); 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); Julien Le Roux, et al., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 WATER RESEARCH 3164 (Mar. 26, 2011); 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); Giovanni Brambilla & Antonietta Martelli, *Update on genotoxicity and carcinogenicity testing of 472 marketed pharmaceuticals*, 681 MUTATION RESEARCH 209 (Sept. 19, 2008); Giovanni Brambilla & Antonietta Martelli, *Genotoxic and carcinogenic risk to humans of drug–nitrite interaction products*, 635 MUTATION RESEARCH 17 (Dec. 6, 2006).

31 Zeng & Mitch, *supra* footnote 19.

II. PARTIES

A. Plaintiffs

1. New Jersey Plaintiff

a. Mary Santorella

26. Plaintiff Mary Santorella is a citizen of New Jersey and resides in Kenilworth, New Jersey.

27. Ms. Santorella first purchased over-the-counter Zantac sometime before 2009 and has until recently taken the drug every other day or as needed to treat her acid reflux.

28. During the time that that she has taken Zantac, Ms. Santorella has generally purchased Zantac in the form of 150 mg tablets at Best Market stores in New Jersey.

29. Ms. Santorella spent approximately $400 on Zantac during the relevant period.

30. If Ms. Santorella had known that taking Zantac would expose her to unsafe quantities of NDMA, she would not have purchased or used the drug.

2. Florida Plaintiffs

a. Michael Burke

31. Plaintiff Michael Burke is a citizen of Florida and resides in Longwood, Florida.

32. Mr. Burke first purchased over-the-counter Zantac in about 2013 or 2014 and has until recently taken the medication to treat his acid reflux.

33. During the five or six years that he has taken Zantac, Mr. Burke has generally purchased Zantac in the form of 150 mg tablets and has taken such tablets one to three times a day.

34. All of Mr. Burke's purchases of Zantac have occurred in Florida, and he has generally purchased the drug at 7-Eleven or CVS stores.

35. Mr. Burke spent approximately $750 on Zantac during the relevant period.

36. If Mr. Burke had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased or used the drug.

b. Stephanie Frasier

37. Plaintiff Stephanie Frasier is a citizen of Florida and resides in Fort Pierce, Florida.

38. Ms. Frasier first purchased over-the-counter Zantac in 2013 and has generally taken the drug two times a day since to treat her acid reflux, except for a brief period when she took the drug three times a day to treat enteritis.

39. Ms. Frasier purchased Zantac in packages of either 75 mg or 150 mg tablets.

40. Ms. Frasier has purchased Zantac mostly at Walmart stores in Florida but recently has purchased Zantac on Amazon as well.

41. Ms. Frasier spent approximately $800 on Zantac during the relevant period.

42. If Ms. Frasier had known that taking Zantac would expose her to unsafe quantities of NDMA, she would not have purchased or used the drug.

c. Richard Harris

43. Richard Harris is a citizen of Florida and resides in Daytona Beach, Florida.

44. Mr. Harris began taking over-the-counter Zantac in 2016 and has taken the drug twice a day since that time to treat stomach issues.

45. Mr. Harris generally purchased packages of the 75 mg tablets of Zantac but may also have purchased different doses.

46. He typically purchased Zantac at Family Dollar.

47. Mr. Harris spent approximately $400 on Zantac during the relevant period.

48. If Mr. Harris had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased or used the drug.

3. Massachusetts Plaintiffs

a. Kassie Benson

49. Kassie Benson is a citizen of Massachusetts and resides in Taunton, Massachusetts.

50. Ms. Benson purchased over-the-counter Zantac in January 2019 and used the drug for a week or two to treat her acid reflux.

51. She purchased Zantac in the form of 150 mg tablets; at first, she took one tablet a day and then went to two.

52. Ms. Benson ceased taking Zantac after she consulted with a doctor who recommended a medication that worked better to treat her acid reflux.

53. Ms. Benson generally purchased Zantac at CVS.

54. She spent approximately $20 on Zantac during the relevant period.

55. If Ms. Benson had known that taking Zantac would expose her to unsafe quantities of NDMA, she would not have purchased or used the drug.

b. Lisa Prisinzano

56. Lisa Prisinzano is a citizen of Massachusetts and resides in Stoughton, Massachusetts.

57. Ms. Prisinzano first purchased over-the-counter Zantac in 2017 or 2018.

58. Since then, she has not used Zantac every day but has taken it occasionally when she experiences acid reflux or heartburn.

59. Ms. Prisinzano typically purchased Zantac packages containing 150 mg tablets of the drug.

60. She spent approximately $50 on Zantac during the relevant period.

61. If Ms. Prisinzano had known that taking Zantac would expose her to unsafe quantities of NDMA, she would not have purchased or used the drug.

B. Defendants

1. Sanofi Defendants

62. 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.

63. 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.

64. 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.

65. 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.

2. Boehringer

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

III. JURISDICTION AND VENUE

67. 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.

68. 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.

69. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) each Defendant transacts business in, is found in, and/or has agents in this district, and because a substantial part of the events giving rise to this action occurred within this district.

IV. FACTUAL ALLEGATIONS

A. A Brief History of Zantac

70. Zantac was developed by Glaxo—now GlaxoSmithKline—and approved for prescription use by the FDA in 1983.[32] 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.[33]

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[32] Wright, *supra* footnote 2, at 26.

[33] *Histamine H2 Antagonist (Oral Route, Injection Route, Intravenous Route)*, MAYO CLINIC (last updated Aug. 1, 2019), https://www.mayoclinic.org/drugs-supplements/histamine-h2-antagonist-oral-route-injection-route-intravenous-route/description/drg-20068584.

71. Due in large part to Glaxo's marketing strategy, Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986.[34] 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."[35] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[36]

72. Zantac became available without a prescription in 1996,[37] and generic versions of the drug (ranitidine) became available the following year.[38] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[39] 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[40]—a 3.1% increase from the previous year.[41]

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

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34 *See* Wright, *supra* footnote 2, at 27.

35 *See* Wright, *supra* footnote 2, at 25.

36 *See* Wright, *supra* footnote 2, at 27.

37 Wright, *supra* footnote 2, at 28.

38 David Ranii, *Generic Zantac on market*, NEWS AND OBSERVER (Aug. 5, 1997).

39 *GlaxoSmithKline – Product Portfolio*, PHARMACEUTICALS COMPANY ANALYSIS (Jan. 21, 2003) (Lexis Advance).

40 *Leading antacid tablet brands in the United States in 2018*, *supra* footnote 3.

41 *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-sales-growth-of-antacid-tablet-brands-in-2013/.

74. As relevant here, Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006,[42] and manufactured and sold the drug in the United States from approximately January 2007 to January 2017.[43]

75. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and have since that time been manufacturing and selling the drug in the United States.[44]

B. The Dangers of N-Nitrosodimethylamine (NDMA)

76. "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."[45]

77. 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

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[42] *Boehringer Ingelheim Pharmaceuticals, Inc. Announces Agreement to Acquire Zantac® from Johnson & Johnson and the Pfizer Consumer Healthcare Business*, BUSINESS WIRE (Oct. 12, 2006).

[43] *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).

[44] *Chattem adds Zantac*, *supra* footnote 433.

[45] *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.

tested so far."[46] NDMA is no longer produced or commercially used in the United States, except for research.[47] In other words, it is only a poison.

78. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[48] 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."[49]

79. 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.[50]

80. 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

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46 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").

47 *Technical Fact Sheet*, *supra* footnote 455.

48 *Technical Fact Sheet*, *supra* footnote 45; 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.

49 *WHO Guidelines*, *supra* footnote 48.

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).

irbesartan—because the medications "contain[ed] nitrosamine impurities that don't meet the [FDA's] safety standards,"[51] which provide that the intake of NDMA should be no more than 96 ng.[52] 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.[53] 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.

81. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying the FDA-recommended GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan[54]—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.[55]

82. 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."[56] Thus, ranitidine produces

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[51] *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.

[52] *FDA Updates and Press Announcements*, *supra* footnote 12.

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

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

[55] *See* Citizen Petition, *supra* footnote 7, at 5; *Combined N-Nitrosodimethylamine*, *supra* footnote 54.

[56] Citizen Petition, *supra* footnote 7, at 19.

NDMA by "react[ing] with itself,"[57] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[58]

C. 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.

83. 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 ever disclosed this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA.

84. 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.[59]

85. 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 should not have been ignored by Defendants.

86. For example, a 2011 scientific study found that, out of eight pharmaceuticals that were observed, "ranitidine showed the strongest potential to form N-nitrosodimethylamine

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57 Citizen Petition, *supra* footnote 7, at 2.

58 Citizen Petition, *supra* footnote 7, at 1.

59 *See, e.g.,* Silvio De Flora, et al., *Genotoxicity of nitrosated ranitidine*, 4(3) Carcinogenesis 255, 260 (1983) (stating that "the potential risk linked with [ranitidine] use is probably negligible"); J Meyrick Thomas, et al., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 28 GUT 726, 737 (1987) ("The most important findings of this study are that . . . N-nitroso compound concentration did not increase during prolonged maintenance treatment with ranitidine . . . ."); Jun Matsuda, *Nitrosamines in gastric juice of patients with gastric ulcer before and during treatment with histamine H_2-receptor antagonists*, 25(2) GASTROENTEROLOGIA JAPONICA 162, 168 (1990) ("The amounts of NDMA and NDEA found in human gastric juice even when patients were given H2-blockers seemed too small to produce carcinogenesis in a short time in man.").

(NDMA)" when present in drinking water during chloramine disinfection.[60] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[61] Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[62]

87. 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."[63]

88. 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."[64] The article noted that these levels of

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60 Shen & Andrews, *supra* footnote 30, at 944. "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.

61 Shen & Andrews, *supra* footnote 30, at 948.

62 Le Roux, *supra* footnote 30, at 3165.

63 Liu, *supra* footnote 30, at 8660.

64 Zeng & Mitch, *supra* footnote 19, at 625. William Mitch is a professor of Civil and Environmental Engineering at Stanford University. *William Mitch,* Stanford University, https://cee.stanford.edu/people/william-mitch (last visited Sept. 13, 2019). Teng Zeng is an Associate Professor of Civil and Environmental Engineering at Syracuse University. *Teng Zeng*, Syracuse University College of Engineering & Computer Science, http://eng-cs.syr.edu/our-departments/civil-and-environmental-engineering/people/faculty/?peopleid=3322 (last visited September 19, 2019).

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."[65] 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.[66] 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."[67] 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."[68]

89. A 2018 scientific review "summariz[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)"[69] again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."[70]

90. 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.

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65 Zeng & Mitch, *supra* footnote 19, at 625.

66 Zeng & Mitch, *supra* footnote 19, at 632.

67 Zeng & Mitch, *supra* footnote 19, at 632–33.

68 Zeng & Mitch, *supra* footnote 19, at 632–33.

69 Sgroi, *supra* footnote 30, at 685.

70 Sgroi, *supra* footnote 30, at 698.

91. Reading this Complaint, one might ask: How did this happen? Why was this drug, which has been taken by millions, allowed to be sold? The answer is that the United States drug regulatory system is largely reliant on the drug manufacturers themselves to perform adequate testing and report adverse events.

92. 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.

93. 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.[71]

94. 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., mutageniticity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product."[72]

95. 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.

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[71] 21 C.F.R. § 314.81(b)(2).

[72] 21 C.F.R. § 314.81(b)(2)(v).

96. 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

97. Plaintiffs bring this action under Federal Rule of Civil Procedure 23(a) and (b)(3), on behalf of themselves and all other similarly situated.

98. Subject to confirmation, clarification, or modification based on discovery to be conducted in this action, the Classes that Plaintiffs seek to represent are defined as follows:

> **The Nationwide Class:** All persons who purchased over-the-counter Zantac in the United States for personal, family, or household use during the Class Period.
>
> **The New Jersey Class:** All persons who purchased over-the-counter Zantac in New Jersey for personal, family, or household use during the Class Period.
>
> **The Florida Class:** All persons who purchased over-the-counter Zantac in Florida for personal, family, or household use during the Class Period.
>
> **The Massachusetts Class:** All persons who purchased over-the-counter Zantac in Massachusetts for personal, family, or household use during the Class Period.

99. For purposes of this action, the Class Period is defined as the period from January 1, 2010 through the present.

100. 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.

101. 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.

102. 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 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."[73]

103. 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.

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

105. 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.

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

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[73] *How Acid Reducers Can Help Treat Heartburn*, WEBMD (June 10, 2017), https://www.webmd.com/heartburn-gerd/h2-blockers-how-acid-reducers-can-help-treat-gerd-symptoms.

a. Whether the Zantac sold by Defendants exposed Plaintiffs and 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 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 Class members are entitled to attorneys' fees, prejudgment interest, and costs, and if so, in what amount.

107. Plaintiffs and 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).

108. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VI. TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Discovery-Rule Tolling

109. Within the period of any applicable statutes of limitation, Plaintiffs and members of the proposed Class could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the high levels of the carcinogen NDMA produced by Zantac.

110. 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 articles that were published in scientific journals. Plaintiffs and Class members 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 Plaintiffs or Class members.

111. Plaintiffs and 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.

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

B. Fraudulent-Concealment Tolling

113. 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.

114. 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.

C. Estoppel

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

116. 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.

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

VII. CLAIMS FOR RELIEF

CLAIMS BROUGHT BY NEW JERSEY PLAINTIFF ON BEHALF OF HERSELF, THE NATIONWIDE CLASS, AND THE NEW JERSEY CLASS

COUNT 1
Violation of New Jersey Consumer Fraud Act
(N.J.S.A. §§ 56:8-1 to -91),
Claim by New Jersey Plaintiff Against All Defendants

118. Plaintiff Mary Santorella ("Plaintiff" for purposes of all claims under New Jersey law) hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

119. This claim is brought by Plaintiff against all Defendants on behalf of themselves and the Nationwide Class and the New Jersey Class (collectively "the Class" for purposes of all claims under New Jersey law).

120. Defendants, Plaintiff, and Class members are "persons" within the meaning of the Consumer Fraud Act.

121. At all relevant times, Defendants conducted trade and commerce in New Jersey and across the United States within meaning of the Consumer Fraud Act.

122. Defendants engaged in "sales" of "merchandise" in New Jersey and across the United States within the meaning of the Act.

123. The Consumer Fraud Act is a cumulative remedy, such that remedies under its provisions can be awarded in addition to those provided under other statutes.

124. The New Jersey Consumer Fraud Act makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with

the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby . . . ."

125. As described in this Complaint, Defendants conduct constitutes "deceptive," "unfair," and "unconscionable" acts or practices in violation of the Consumer Fraud Act.

126. Defendants' practices violated the Act for, among other things, the following reasons:

a. Defendants concealed from Plaintiff and Class members the material fact that Zantac was defective, and as such, was not of merchantable quality.

b. Defendants engaged in unconscionable commercial practices in failing to disclose material information discussed above regarding the relationship between Zantac and NDMA.

127. Defendants consciously omitted to disclose material facts to Plaintiff and Class members regarding the defects in Zantac.

128. Defendants' unconscionable conduct described herein includes the omission and concealment of material facts concerning the defects in Zantac.

129. Defendants intended that Plaintiff and Class members would rely on their omissions and misrepresentations so that Plaintiff and Class members would purchase Zantac.

130. Had Defendants disclosed all material information regarding the defect in Zantac to Plaintiff and Class members, they would not have purchased Zantac.

131. The foregoing acts, omissions, and practices proximately caused Plaintiff and Class members to suffer an ascertainable loss in the form of, among other things, the money they paid for Zantac.

132. Plaintiff and Class members are entitled to "a refund of all moneys acquired by means of" Defendants' unlawful practices,[74] together with other appropriate penalties, including treble damages, attorneys' fees, and costs of the suit.

133. Defendants knew that the Zantac they were manufacturing and distributing was defective, and was not suitable for its intended use. Defendants had notice of this fact through numerous scientific articles showing that Zantac produces NDMA. Defendants nonetheless failed to warn Plaintiff and Class members about this defect despite having a duty to do so.

134. By failing to disclose and by actively concealing the defect in Zantac, which they marketed as safe, Defendants engaged in unfair and deceptive business practices in violation of the Consumer Fraud Act.

135. In the course of Defendants' business, they willfully failed to disclose and actively concealed the dangerous risk posed by the defect in Zantac

136. Defendants' unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff and Class members, about the true safety of Zantac.

137. Defendants intentionally and knowingly misrepresented material facts regarding Zantac with the intent to mislead Plaintiff and Class members.

138. Defendants knew or should have known that their conduct violated the Consumer Fraud Act.

139. As alleged above, Defendants made material statements about the safety of Zantac that were either false or misleading.

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[74] N.J.S.A. § 56:8-2.11.

140. Defendants had a duty to disclose to Plaintiff and Class members the truth about the safety of Zantac.

141. Had Plaintiff and Class members been aware of the NDMA exposure caused by Zantac, they would not have purchased Zantac.

142. Defendants' concealment of the defects in Zantac was material to Plaintiff and Class members.

143. Plaintiff and Class members suffered ascertainable loss caused by Defendants' misrepresentations and concealment of and failure to disclose the defect in Zantac.

144. As a direct and proximate result of Defendants' violations of the Consumer Fraud Act, Plaintiff and Class members have suffered injury-in-fact and actual damages, as alleged above.

145. Plaintiff and Class members seek punitive damages from Defendants because Defendants' conduct was egregious and unconscionable. Defendants' conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in reckless disregard of the rights of Plaintiff and Class members.

146. Because Defendants' unconscionable conduct caused injury to Plaintiff and Class members, Plaintiff and Class members seek a refund for their purchases of Zantac, together with appropriate penalties, including treble damages, reasonable attorneys' fees, costs, and any other legal or equitable relief that the Court deems just and appropriate.

COUNT 2
Fraudulent Concealment (Under New Jersey Common Law),
Claim by New Jersey Plaintiff Against All Defendants

147. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

148. The Plaintiff brings this claim against all Defendants on behalf of themselves and the Nationwide Class and the New Jersey Class.

149. Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of NDMA.

150. Defendants affirmatively misrepresented to Plaintiff and Class members in advertising and other forms of communication, including standard and uniform material provided with the drug's packaging, that Zantac had no significant defects and was safe to consume.

151. Defendants knew about the defect in Zantac when they made these representations.

152. Defendants had a duty to disclose that Zantac contains a fundamental defect as alleged herein, because the defect created a risk to consumers' health and Plaintiff and Class members relied on Defendants' material representations.

153. At all relevant times, Defendants held out Zantac to be free from defects and to be a "safe" drug for consumers. Defendants' touted the many benefits and advantages of Zantac, but failed to disclose important facts related to the defect. This made Defendants' other statements about Zantac deceptive.

154. Plaintiff and Class members did not know of the defect in Zantac, and Defendants actively concealed the defect from them.

155. Plaintiff and Class members reasonably relied upon Defendants' deception. They had no way of knowing that Defendants' representations were false, misleading, or incomplete. As consumers, Plaintiff and Class members did not, and could not, unravel Defendants' deception on their own. Rather, Defendants intended to deceive Plaintiff and Class members by concealing the true facts about Zantac exposing consumers to high levels of the carcinogen NDMA.

156. Defendants' false representations and omissions were material to consumers because they concerned a quality of Zantac—safety—that played a significant role in the value of Zantac to consumers.

157. Defendants had a duty to disclose the Zantac defect because Defendants knew that the defect was not known to or reasonably discoverable by Plaintiff or Class members.

158. Plaintiff and Class members were unaware of the omitted material facts referenced herein, and they would not have acted as they did if they had known of the concealed or suppressed facts, in that they would not have purchased Zantac and would have taken other affirmative steps in light of the information concealed from them.

159. Because of Defendants' concealment and suppression of facts, Plaintiff and Class members sustained damage because they would not have purchased or consumed Zantac but for Defendants' actions.

160. Plaintiff and Class members seek damages, attorneys' fees, court costs, and any other legal or equitable relief that the Court deems just and appropriate.

161. Defendants' acts were done wantonly, maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiff's and Class members' rights, in order to enrich themselves. Plaintiff and Class members request an assessment of punitive damages in an amount sufficient to deter such conduct in the future.

COUNT 3
Breach of Implied Warranties Under New Jersey Uniform Commercial Code (N.J.S.A. §§ 12A:1-101 to 12A:2-725), Claim by New Jersey Plaintiff Against All Defendants

162. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

163. This claim is brought against all Defendants by Plaintiff on behalf of herself, the Nationwide Class, and the New Jersey Class.

164. Under the New Jersey Uniform Commercial Code, a warranty of merchantability is implied in every contract for the sale of goods. A contract for the sale of goods need not be written but "may be made in any manner sufficient to show agreement, including conduct by both parties which recognizes the existence of such a contract." Furthermore, the New Jersey UCC does not require privity between Plaintiff and Defendants.

165. An implied warranty of merchantability is breached when the good or product at issue is defective or not fit for the ordinary purpose for which it is intended.

166. The Zantac manufactured and distributed by Defendants is and was defective because it exposes persons who take the drug to high levels of the carcinogen NDMA. Thus, Zantac is defective and not fit for the ordinary purpose for which it is intended.

167. At the time that Defendants sold and warranted Zantac, they knew that Zantac was defective and not fit for the ordinary purpose for which it is intended. Nonetheless, Defendants wrongfully and fraudulently concealed these material facts from Plaintiff and Class members. Plaintiff and Class members were therefore induced to purchase Zantac under false or fraudulent pretenses.

168. Because of Defendants' breach of implied warranty, Plaintiff and Class members seek a full refund of the purchase price of all Zantac they purchased that was manufactured and distributed by Defendants.

169. Defendants have been provided notice of these issues by (among other things) communications from the FDA, scientific and news articles, and this Complaint, as well as a complaint filed in the Northern District of California.

170. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff and Class members have been damaged and request all damages they are entitled to under the Uniform Commercial Code, as well as any other legal or equitable relief that the Court deems just and appropriate.

CLAIMS BROUGHT BY FLORIDA PLAINTIFFS ON BEHALF OF THEMSELVES AND THE FLORIDA CLASS

COUNT 4
Violation of Florida Deceptive and Unfair Practices Act (Fla. Stat. §§ 501.201–.213), Claim by Florida Plaintiffs Against the Sanofi Defendants

171. Plaintiffs Michael Burke, Stephanie Frasier, and Richard Harris ("Plaintiffs" for purposes of all Florida claims) incorporate by reference all paragraphs as though fully set forth herein.

172. The Florida Plaintiffs bring this claim against the Sanofi Defendants on behalf of themselves and the Florida Class ("the Class" for purposes of all Florida claims).

173. Plaintiffs and members of the Class are "consumers" under the Florida Deceptive and Unfair Trade Practices Act.[75]

174. The Sanofi Defendants engaged in "trade or commerce" as defined by the Act.[76]

175. Section 501.204(1) of the Florida Deceptive and Unfair Trade Practices Act prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." The Sanofi Defendants participated in unfair and deceptive trade practices that violated the Act.

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75 Fla. Stat. Ann. § 501.203(7).

76 *Id.* § 501.203(8).

176. By not disclosing the defective nature of Zantac, the Sanofi Defendants willfully and knowingly engaged in unfair and deceptive acts in the conduct of trade and commerce within the State of Florida.

177. In purchasing Zantac, Plaintiffs and Class members were deceived by the Sanofi Defendants' failure to disclose that Zantac was defective because it exposed users to high levels of the carcinogen NDMA.

178. Plaintiffs and Class members reasonably relied upon the Sanofi Defendants' false misrepresentations and omissions. They had no way of knowing that the Sanofi Defendants' representations were false, misleading, and incomplete. The Sanofi Defendants willfully and knowingly engaged in a pattern of deception and public silence in the face of a known defect with Zantac. Plaintiffs and Class members did not, and could not have, unravel the Sanofi Defendants' deception on their own.

179. The Sanofi Defendants' unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers.

180. The Sanofi Defendants willfully and knowingly misrepresented material facts regarding Zantac with intent to mislead Plaintiffs and Class members.

181. The Sanofi Defendants knew or should have known that their conduct violated the Florida Deceptive and Unfair Practices Act.

182. The Sanofi Defendants owed Plaintiffs and Class members a duty to disclose the truth about the defect in Zantac because that defect presented a harm to consumer health, and Plaintiffs and Class members relied on the Sanofi Defendants' material misrepresentations and omissions regarding the drug's safety.

183. Plaintiffs and Class members were injured and suffered ascertainable loss, injury-in-fact, and actual damages as a proximate result of the Sanofi Defendants' conduct because Plaintiffs and Class members bought a drug—Zantac—that they would not have purchased but for the Sanofi Defendants' material misrepresentations and omissions.

184. The Sanofi Defendants' violations of the Act cause continuing injuries to Plaintiffs and Class members. The Sanofi Defendants' unlawful acts and practices complained of herein affect the public interest.

185. Plaintiffs and Class members seek damages and treble damages for the Sanofi Defendants' knowing violations.

186. Plaintiffs and Class members also seek court costs and attorneys' fees.

COUNT 5
Fraudulent Concealment (Under Florida Common Law),
Claim by Florida Plaintiffs Against the Sanofi Defendants

187. Plaintiffs incorporates by reference all preceding allegations as though fully set forth herein.

188. The Florida Plaintiffs bring this claim against the Sanofi Defendants on behalf of the Florida Class.

189. The Sanofi Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of NDMA.

190. The Sanofi Defendants affirmatively misrepresented to Plaintiffs and Class members in advertising and other forms of communication, including standard and uniform material provided with the drug's packaging, that Zantac had no significant defects and was safe to consume.

191. The Sanofi Defendants knew about the defect in Zantac when they made these representations.

192. The Sanofi Defendants had a duty to disclose that Zantac contains a fundamental defect as alleged herein, because the defect created a risk to consumers' health, and Plaintiffs and Class members relied on the Sanofi Defendants' material representations.

193. At all relevant times, the Sanofi Defendants held out Zantac to be free from defects and to be a "safe" drug for consumers. The Sanofi Defendants touted the many benefits and advantages of Zantac, but failed to disclose important facts related to the defect. This made the Sanofi Defendants' other statements about Zantac deceptive.

194. Plaintiffs and Class members did not know of the defect in Zantac, and the Sanofi Defendants actively concealed the defect from them.

195. Plaintiffs and Class members reasonably relied upon the Sanofi Defendants' deception. They had no way of knowing that the Sanofi Defendants' representations were false, misleading, or incomplete. As consumers, Plaintiffs and Class members did not, and could not, unravel the Sanofi Defendants' deception on their own. Rather, the Sanofi Defendants intended to deceive Plaintiffs and Class members by concealing the true facts about Zantac exposing consumers to high levels of the carcinogen NDMA.

196. The Sanofi Defendants' false representations and omissions were material to consumers because they concerned a quality of Zantac—safety—that played a significant role in the value of Zantac to consumers.

197. The Sanofi Defendants had a duty to disclose the Zantac defect because they knew that the defect was not known to or reasonably discoverable by Plaintiffs or Class members.

198. Plaintiffs and Class members were unaware of the omitted material facts referenced herein, and they would not have acted as they did if they had known of the concealed or suppressed

facts, in that they would not have purchased Zantac and would have taken other affirmative steps in light of the information concealed from them.

199. Because of the Sanofi Defendants' concealment and suppression of facts, Plaintiffs and Class members sustained damage because they would not have purchased or consumed Zantac but for the Sanofi Defendants' actions.

200. Plaintiffs and Class members seek damages, attorneys' fees, court costs, and any other legal or equitable relief that the Court deems just and appropriate.

201. The Sanofi Defendants' acts were done wantonly, maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' and Class members' rights, and in order to enrich the Sanofi Defendants. Plaintiffs and Class members seek an assessment of punitive damages in an amount sufficient to deter such conduct in the future.

CLAIMS BROUGHT BY MASSACHUSETTS PLAINTIFFS ON BEHALF OF THEMSELVES AND THE MASSACHUSETTS CLASS[77]

COUNT 6
Fraudulent Concealment (under Massachusetts Common Law), Claim by Massachusetts Plaintiffs Against the Sanofi Defendants

202. Plaintiffs Kassie Benson and Lisa Prisinzano ("Plaintiffs" for purposes of all Massachusetts claims) hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

203. This claim is brought by the Massachusetts Plaintiffs against the Sanofi Defendants on behalf of themselves and the Massachusetts Class ("the Class" for purposes of all Massachusetts claims).

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[77] On September 20, 2019, Plaintiffs sent a notice letter under Massachusetts General Laws Ch. 93A, § 9(3) to all Defendants. Pursuant to Massachusetts General Laws Ch. 93A, § 9, if Defendants do not rectify their conduct within 30 days, Plaintiffs intend to amend this Complaint to add claims under the Massachusetts Regulation of Business Practice and Consumer Protection Act.

204. The Sanofi Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of NDMA.

205. The Sanofi Defendants affirmatively misrepresented to Plaintiffs and Class members in advertising and other forms of communication, including standard and uniform material provided with the drug's packaging, that Zantac had no significant defects and was safe to consume.

206. The Sanofi Defendants knew about the defect in Zantac when they made these representations.

207. The Sanofi Defendants had a duty to disclose that Zantac contains a fundamental defect as alleged herein, because the defect created a risk to consumers' health, and Plaintiffs and Class members relied on the Sanofi Defendants' material representations.

208. At all relevant times, the Sanofi Defendants held out Zantac to be free from defects and to be a "safe" drug for consumers. The Sanofi Defendants touted the many benefits and advantages of Zantac, but failed to disclose important facts related to the defect. This made the Sanofi Defendants' other statements about Zantac deceptive.

209. Plaintiffs and Class members did not know of the defect in Zantac, and the Sanofi Defendants actively concealed the defect from them.

210. Plaintiffs and Class members reasonably relied upon the Sanofi Defendants' deception. They had no way of knowing that the Sanofi Defendants' representations were false, misleading, or incomplete. As consumers, Plaintiffs and Class members did not, and could not, unravel the Sanofi Defendants' deception on their own. Rather, the Sanofi Defendants intended to deceive Plaintiffs and Massachusetts Class members by concealing the true facts about Zantac exposing consumers to high levels of the carcinogen NDMA.

211. The Sanofi Defendants' false representations and omissions were material to consumers because they concerned a quality of Zantac—safety—that played a significant role in the value of Zantac to consumers.

212. The Sanofi Defendants had a duty to disclose the Zantac defect because the Sanofi Defendants knew that the defect was not known to or reasonably discoverable by Plaintiffs or Class members.

213. Plaintiffs and Class members were unaware of the omitted material facts referenced herein, and they would not have acted as they did if they had known of the concealed or suppressed facts, in that they would not have purchased Zantac and would have taken other affirmative steps in light of the information concealed from them.

214. Because of the Sanofi Defendants' concealment and suppression of facts, Plaintiffs and Class members sustained damages because they would not have purchased or consumed Zantac but for the Sanofi Defendants' actions.

215. Plaintiffs and the Class members seek damages, attorneys' fees, court costs, and any other legal or equitable relief that the Court deems just and appropriate. The Sanofi Defendants' acts were done wantonly, maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' and Class members' rights, in order to enrich the Sanofi Defendants. Plaintiffs seek an assessment of punitive damages in an amount sufficient to deter such conduct in the future.

COUNT 7
Breach of Implied Warranties under Massachusetts Uniform Commercial Code (Mass. Gen. Laws Ann. ch. 106, §§ 1-101 to 2-725),
Claim by Massachusetts Plaintiffs Against the Sanofi Defendants

216. Plaintiffs hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

217. This claim is brought by the Massachusetts Plaintiffs against the Sanofi Defendants on behalf of themselves and the Massachusetts Class.

218. Under the Massachusetts Uniform Commercial Code, a warranty of merchantability is implied in every contract for the sale of goods.[78] A contract for the sale of goods need not be written but "may be made in any manner sufficient to show agreement, including conduct by both parties which recognizes the existence of such a contract."[79] Furthermore, the Massachusetts Uniform Commercial Code does not require privity between Plaintiffs and the Sanofi Defendants.[80]

219. An implied warranty of merchantability is breached when the good or product at issue is defective or not fit for the ordinary purpose for which it is intended.[81]

220. The Zantac manufactured and distributed by the Sanofi Defendants is and was defective because it exposes persons who take the drugs to high levels of the carcinogen NDMA. Thus, Zantac is defective and not fit for the ordinary purpose for which it is intended.

221. At the time that the Sanofi Defendants sold and warranted Zantac, they knew that Zantac was defective and not fit for the ordinary purpose for which it is intended. Nonetheless, the Sanofi Defendants wrongfully and fraudulently concealed these material facts from Plaintiff and Class members. Plaintiff and Class members were therefore induced to purchase Zantac under false or fraudulent pretenses.

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78 Mass. Gen. Laws. Ann. ch. 106, § 2-314.

79 *Id.* § 2-204.

80 *Id.* § 2-318.

81 *See id.* § 2-314.

222. Because of the Sanofi Defendants' breach of implied warranty, Plaintiffs and Class members seek a full refund of the purchase price of all Zantac they purchased that was manufactured and distributed by the Sanofi Defendants.

223. The Sanofi Defendants have been provided notice of these issues by (among other things) communications from the FDA, scientific and news articles, and this Complaint, as well as a complaint filed in the Northern District of California.

224. As a direct and proximate result of the Sanofi Defendants' breach of implied warranty, Plaintiffs and Class members have been damaged and request all damages they are entitled to under the Uniform Commercial Code, as well as any other legal or equitable relief that the Court deems just and appropriate.

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. A determination that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure Rule 23 and for an order certifying this case as a class action and appointing Plaintiffs as Class representatives as reflected above;

B. A declaration that Defendants' failure to disclose to consumers that Zantac produces unsafe levels of NDMA was unfair, deceptive, fraudulent, wrongful, and unlawful;

C. Restitution for all purchases of Zantac by Plaintiffs and the Class, in an amount to be determined at trial;

D. Disgorgement of the ill-gotten gains derived by Defendants from their misconduct;

E. Actual damages;

F. Statutory damages;

G. Punitive damages;

H. Treble damages;

I. Compensatory damages caused by Defendants' unfair or deceptive practices; along with exemplary damages to Plaintiffs and each Class member for each violation;

J. A permanent injunction 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;

K. Pre-judgment and post-judgment interest at the maximum rate permitted by applicable law;

L. An order awarding Plaintiffs and the Class their attorney's fees, costs, and expenses incurred in connection with this action; and

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

IX. JURY DEMAND

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

Dated: September 20, 2019

Respectfully submitted,

By: /s/ James E. Cecchi

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