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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

Christina Garza, Pankaj Khetarpal, Corina Lingerfelt, and Justin Rowe,

Plaintiffs,

v.

Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; Chattem, Inc.; and Boehringer Ingelheim Pharmaceuticals, Inc.,

Defendants.

Civil Action No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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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).

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.

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[1] *Ranitidine hydrochloride – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE (last visited Sept. 13, 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. OF 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.

These companies never 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."

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.[7]

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

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."[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]

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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).

[8] *Id.*

[9] *Id.* at 2.

[10] *Id.*

[11] *Id.*

7. The FDA recently announced a permissible intake limit of **96 ng** of NDMA per day.[12] 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."[13]

8. 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 amount that can be safely ingested daily.

9. "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]

10. 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.[17]

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[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), 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 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 at 6.

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

[16] *Id.*

[17] This quantity also can be expressed as 280 mg or 0.28 g 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.

11. Zantac is used not only by adults but is also given to children and teenagers to treat gastroesophageal reflux, among other things.[18]

12. 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.[19] Recent peer-reviewed scientific literature has demonstrated the existence of dangerous levels of NDMA in the urine of those who have taken ranitidine.[20]

13. 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.

14. 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[21] and that a person who consumes ranitidine has a 400-fold increase of NDMA

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[18] *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.

[19] Citizen Petition at 6–7.

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

[21] *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

concentration in their urine.[22]

15. 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.

16. 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 California between January 1, 2010 and the present.

17. 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.

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

II. PARTIES

A. Plaintiffs

1. Christina Garza

19. Plaintiff Christina Garza is a citizen of the State of California and resides in Fontana, California.

20. Ms. Garza first purchased over-the-counter Zantac in approximately 2015 at either a Target or Walmart in California, and took the drug consistently for the next two years.

(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).

[22] Zeng & Mitch, *supra* footnote 20.

21. Ms. Garza purchased over-the-counter Zantac that was manufactured and distributed by Defendant Boehringer and by the Sanofi Defendants.

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

2. Pankaj Khetarpal

23. Plaintiff Pankaj Khetarpal is a citizen of the State of California and resides in San Diego, California.

24. Mr. Khetarpal first started taking Zantac in approximately 2007.

25. As recently as August 2019, Mr. Khetarpal was purchasing over-the-counter Zantac from either Costco or CVS in California, and taking a 150 mg dose three to five times per week.

26. Mr. Khetarpal purchased over-the-counter Zantac that was manufactured and distributed by Defendant Boehringer and by the Sanofi Defendants.

27. Mr. Khetarpal would not have purchased or used Zantac if he had known that the drug would expose him to unsafe levels of NDMA.

3. Corina Lingerfelt

28. Plaintiff Corina Lingerfelt is a citizen of the State of California and resides in San Jose, California.

29. Ms. Lingerfelt started taking over-the-counter Zantac in approximately 2009; since then, she has consistently purchased large packages of 150 mg Zantac tablets at least three times a year, generally at either Walmart or Costco in California.

30. During that ten-year period, Ms. Lingerfelt took Zantac tablets to treat her heartburn.

31. Thus, Ms. Lingerfelt purchased over-the-counter Zantac that was manufactured and distributed by Defendant Boehringer and by the Sanofi Defendants.

32. Ms. Lingerfelt would not have purchased or used Zantac if she had known that the drug would expose her to unsafe levels of NDMA.

4. Justin Rowe

33. Plaintiff Justin Rowe is a citizen of the State of California and resides in Garden Grove, California.

34. Mr. Rowe purchased over-the-counter Zantac at CVS and Walgreens pharmacies in California for approximately two years beginning in about 2016.

35. During that two-year period, Mr. Rowe consistently took two 150 mg tablets of Zantac a day.

36. Mr. Rowe purchased over-the-counter Zantac that was manufactured and distributed by Defendant Boehringer and by the Sanofi Defendants.

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

B. Defendants

1. Sanofi Defendants

38. 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.

39. 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.

40. 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.

41. 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.

2. Boehringer

42. 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

43. 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.

44. 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.

45. 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 Northern District of California, and because some of the actions giving rise to this complaint took place within this district.

46. Intradistrict Assignment: Assignment to the San Francisco, Oakland or San Jose divisions of this Court is proper pursuant to Northern District of California Local Rule 3-2(d) because a substantial part of the events giving rise to the claims arose in this District.

IV. FACTUAL ALLEGATIONS

A. A Brief History of Zantac

47. Zantac was developed by Glaxo—now GlaxoSmithKline—and approved for prescription use by the FDA in 1983.[23] 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.[24]

48. Due in large part to Glaxo's marketing strategy, Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986.[25] 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."[26] Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[27]

49. Zantac became available without a prescription in 1996,[28] and generic versions of the drug (ranitidine) became available the following year.[29] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[30] 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,

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

[24] *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.

[25] *See* Wright, *supra* footnote 2, at 27.

[26] *See* Wright, *supra* footnote 2, at 25

[27] *See* Wright, *supra* footnote 2, at 27.

[28] Wright, *supra* footnote 2, at 28.

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

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

with sales of Zantac 150 totaling $128.9 million[31]—a 3.1% increase from the previous year.[32]

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

51. As relevant here, Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006,[33] and manufactured and sold the drug in the United States—including in California—from approximately January 2007 to January 2017.[34]

52. 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, including in California.[35]

B. The Dangers of N-Nitrosodimethylamine (NDMA)

53. "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."[36]

54. 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

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

[32] *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/.

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

[34] *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).

[35] *Chattem adds Zantac*, *supra* footnote 34.

[36] *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.

animal tested so far."[37] NDMA is no longer produced or commercially used in the United States, except for research.[38] In other words, it is only a poison.

55. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[39] 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."[40]

56. 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.[41]

57. 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

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[37] 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").

[38] *Technical Fact Sheet*, *supra* footnote 36.

[39] *Technical Fact Sheet*, *supra* footnote 36; 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.

[40] *WHO Guidelines*, *supra* footnote 39.

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

[FDA's] safety standards,"[42] which provide that the intake of NDMA should be no more than 96 ng.[43] 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.[44] 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.

58. 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[45]—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.[46]

59. 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."[47] Thus, ranitidine produces NDMA by "react[ing] with itself,"[48] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[49]

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[42] *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.

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

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

[45] *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.

[46] *See* Citizen Petition at 5; *Combined N-Nitrosodimethylamine*, *supra* footnote 45.

[47] Citizen Petition at 19.

[48] Citizen Petition at 2.

[49] Citizen Petition at 1, 6.

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.

60. 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.

61. 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.[50]

62. 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.

63. 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.[51] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior]

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[50] *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.").

[51] Shen & Andrews, *supra* footnote 21, 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.

literature."[52] Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[53]

64. 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."[54]

65. 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."[55] 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."[56] 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.[57] The authors of the study concluded that "a more comprehensive risk assessment"—such as "[e]pidemiological studies evaluating cancer

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[52] Shen & Andrews, *supra* footnote 21, at 948.

[53] Le Roux, *supra* footnote 21, at 3165.

[54] Liu, *supra* footnote 21, at 8660.

[55] Zeng & Mitch, *supra* footnote 20, 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 13, 2019).

[56] Zeng & Mitch, *supra* footnote 20, at 625.

[57] Zeng & Mitch, *supra* footnote 20, at 632.

risk, particularly bladder cancer, attributable to the long-term use of ranitidine"— was needed because of "the widespread use of ranitidine."[58] 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."[59]

66. A 2018 scientific review "summariz[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)"[60] again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."[61]

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

68. 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.

69. 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.

70. 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

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[58] Zeng & Mitch, *supra* footnote 20, at 632–33.

[59] Zeng & Mitch, *supra* footnote 20, at 632–33.

[60] Sgroi, *supra* footnote 21, at 685.

[61] Sgroi, *supra* footnote 21, at 698.

> 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.[62]

71. 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."[63]

72. 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.

73. 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

74. 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 California who purchased over-the-counter Zantac for personal, family, or household use during the Class Period.

75. 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.

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[62] 21 C.F.R. § 314.81(b)(2).

[63] 21 C.F.R. § 314.81(b)(2)(v).

76. 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.

77. 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."[64]

78. 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.

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

80. 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.

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[64] *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.

81. 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 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.

82. 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).

83. 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

84. 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.

85. 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.

86. 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.

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

B. Fraudulent-Concealment Tolling

88. 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.

89. 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

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

91. 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.

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

VII. CLAIMS FOR RELIEF

COUNT 1: VIOLATION OF CALIFORNIA LEGAL REMEDIES ACT (CAL. CIV. CODE §§ 1750–85), CLAIM BY ALL PLAINTIFFS AGAINST ALL DEFENDANTS

93. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this complaint.

94. This claim is brought by all Plaintiffs against all Defendants on behalf of residents of California who are members of the Class ("California Class members").

95. The California Legal Remedies Act prohibits "unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that results in the sale or lease of goods or services to any consumer."[65] The prohibited unfair or deceptive acts or practices include, among others, (a) "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have,"[66] and (b) "[r]epresenting that goods or services are of a particular standard, quality, or grade . . . if they are of another."[67]

96. Each Defendant is a "person" under the Legal Remedies Act.[68]

97. The Plaintiffs and Class members each purchased one or more Zantac products at issue and are "consumers" under the Legal Remedies Act.[69]

98. As alleged in this Complaint, Defendants' failure to disclose—by labeling or otherwise—the NDMA risk presented by Zantac constitutes both "unfair" and "deceptive" acts in violation of the Legal Remedies Act.

99. As described herein, Defendants' conduct was and is a violation of the Legal Remedies Act. Defendants' conduct violates at least the following provisions of the Act:

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[65] Cal. Civ. Code § 1770.

[66] *Id.* § 1770(a)(5).

[67] *Id.* § 1770(a)(7).

[68] *Id.* § 1761(c).

[69] *Id.* § 1761(d).

a. California Civil Code § 1770(a)(5): Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have full refund for all Zantac purchased by Plaintiffs and Class members.

b. California Civil Code 1770(a)(7): Representing that goods or services are of a particular standard, quality, or grade if they are of another.

100. Defendants misrepresented and omitted material facts regarding Zantac—specifically regarding its exposing consumers to NDMA—with an intent to mislead Plaintiffs and Class members.

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

102. Plaintiffs and Class members had no way of knowing Defendants' representations regarding Zantac were false, misleading, and incomplete.

103. As alleged herein, Defendants 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, unravel Defendants' deception on their own.

104. Defendants knew or should have known that their conduct violated the California Legal Remedies Act.

105. Defendants had a duty to disclose the truth about the NDMA levels produced by Zantac because this defect in the drug creates a risk to consumers' health, and Plaintiffs and Class members relied on Defendants' material misrepresentations and omissions regarding the safety of Zantac.

106. Defendants' conduct proximately caused injury to Plaintiffs and Class members who purchased over-the-counter Zantac.

107. Plaintiffs and Class members were injured and suffered ascertainable loss, injury-in-fact, and/or actual damages as a proximate result of Defendants' conduct in that Plaintiffs

would not have purchased Zantac had they known that the drug exposed them to high levels of NDMA.

108. Defendants' unlawful acts and practices complained of herein affect the public interest.

109. The facts concealed and omitted by Defendants from Plaintiffs and 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.

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

111. The California Plaintiffs and Class members seek an order under the Legal Remedies Act[70] enjoining Defendants 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.

112. On September 13, 2019, Plaintiffs sent a notice letter under California Civil Code § 1782 to all Defendants.

113. Pursuant to California Civil Code § 1782, if Defendants do not rectify their conduct within 30 days, Plaintiffs intend to amend this Complaint to add claims under the Legal Remedies Act for:

a. A full refund for all Zantac purchased by Plaintiffs and Class members;

b. Actual damages;

c. Restitution of money to Plaintiffs and Class members;

d. Punitive damages;

[70] *Id.* §§ 1782(d), 1770.

e. An additional award of up to $5,000 for each Plaintiff and Class member who is a senior citizen;

f. Attorneys' fees and costs; and

g. Other relief that this Court deems just and proper.

COUNT 2: VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW

(CAL. BUS. & PROF. CODE §§ 17200–17594),

CLAIM BY ALL PLAINTIFFS AGAINST ALL DEFENDANTS

114. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

115. This claim is brought by all Plaintiffs against all Defendants on behalf of residents of California who are members of the Class.

116. California's Unfair Competition Law prohibits "unlawful, unfair, or fraudulent business acts or practices."[71]

117. Defendants violated the Unfair Competition Law by committing an unlawful act—their violation of California's Legal Remedies Act, as described above.

118. Defendants' failure to disclose to Plaintiffs and Class members the NDMA levels present in Zantac also is fraudulent—and hence a violation of the Unfair Competition Law—because it was likely to deceive members of the public into believing that the drug would not expose them to the known carcinogen NDMA.

119. Defendants' failure to disclose these risks to Plaintiffs and Class members also violates the Unfair Competition Law because it is unfair given that the harm to consumers—exposure to high levels of a carcinogen without the consumers' knowledge—outweighs the medicinal benefits provided by Zantac, a drug for which there are numerous substitutes.

120. Defendants' actions, as set forth above, occurred within the conduct of their business and in trade or commerce.

[71] Cal. Bus. & Prof. Code § 17200.

121. Defendants knowingly and intentionally misrepresented and omitted material facts regarding Zantac with the intent of misleading Plaintiffs and Class members.

122. In purchasing over-the-counter Zantac, Plaintiffs and Class members were deceived by Defendants' failure to disclose that the drug exposed consumers to high levels of NDMA.

123. Plaintiffs and Class members reasonably relied on Defendants' false misrepresentations and omissions. They had no way of knowing that Defendants' representations were false, misleading, and incomplete. As alleged herein, Defendants 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, unravel Defendants' deception on their own.

124. Defendants knew or should have known that its conduct violated the Unfair Competition Law.

125. Defendants owed Plaintiffs and Class members a duty to disclose the truth about Zantac exposing consumers to NDMA because Plaintiffs and Class members relied on Defendants' material misrepresentations and omissions.

126. Defendants' conduct proximately caused injury to Plaintiffs and Class members who purchased over-the-counter Zantac.

127. Plaintiffs and Class members were injured and suffered ascertainable loss, injury-in-fact, and/or actual damages as a proximate result of Defendants' conduct in that Plaintiffs would not have purchased Zantac had they known that the drug exposed them to high levels of NDMA.

128. Defendants' unlawful acts and practices complained of herein affect the public interest.

129. The facts concealed and omitted by Defendants from Plaintiffs and 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.

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

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

132. Under the Unfair Competition Law, the Court may "restore to any person in interest any money or property, real or personal, which may have been acquired by means of" a violation of the statute.[72]

133. Plaintiffs request that this Court enter such orders or judgments as may be appropriate, including:

a. a declaratory judgment that each Defendant has violated the Unfair Competition Law; an order enjoining Defendants from continuing their unfair, unlawful, and/or fraudulent trade practices; and

b. an order restoring to Plaintiffs any money lost as result of each Defendant's unfair, unlawful, and/or fraudulent trade practices, including restitution and disgorgement of any profits Defendants received as a result of their unfair, unlawful, or fraudulent practices, and for any other relief as may be just and proper.[73]

134. Plaintiffs also request attorneys' fees, which the Court "may award attorneys' fees to a successful party against one or more opposing parties in any action which has resulted in the enforcement of an important right affecting the public interest if: (a) a significant benefit, whether pecuniary or nonpecuniary, has been conferred on the general public or a large class of persons, (b) the necessity and financial burden of private enforcement . . . are such as to make the award appropriate, and (c) such fees should not in the interest of justice be paid out of the recovery, if any."[74]

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[72] Cal. Bus. & Prof. Code § 17203.

[73] *See id.* § 17203; Cal. Civ. Proc. Code § 384; Cal. Civ. Code § 3345.

[74] Cal. Civ. Proc. Code § 1021.5.

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 13, 2019

Respectfully submitted,

By: */s/ Shana E. Scarlett*

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