UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHELLE COGGINS and SANDRA R. WEEKS, individually and on behalf of all others similarly situated, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; CHATTEM, INC.; and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; and DOES 1 through 20, inclusive, Defendants.	Civil Action No. 3:19-cv-20060 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Michelle Coggins and Sandra R. Weeks ("Plaintiffs") bring this Class Action Complaint against Defendants SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; CHATTEM, INC.; and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (collectively "Defendants" or "Sanofi"), on behalf of themselves and all other others similarly situated, and allege as follows:

NATURE OF ACTION

1. Plaintiffs bring this class action against Sanofi for manufacturing and selling Zantac, a heartburn medication used by millions of Americans. Even though Sanofi had reason to know that the drug contained a known carcinogen, it failed to warn consumers. There is no question that if consumers had known this information, they wouldn't have purchased the drug as there are many safer alternatives on the market.

2. Zantac is the brand name of a drug called Ranitidine. Sanofi has known for years that Ranitidine could contain the carcinogen known as N-nitrosodimethylamine (NDMA). This much was made clear in at least one study three years ago by scientists at Stanford University.[1]

3. But the risks posed by Ranitidine were not widely known to the public, and Sanofi had no warning on its label.

4. This changed when a pharmacy conducting its own testing made public headlines by reporting that Zantac had unacceptable levels of the carcinogen in every batch it tested.[2] The pharmacy went so far as to file a petition urging the FDA to recall the drug.[3] It stated in no uncertain terms that Zantac posed a significant risk to millions of Americans because it is a heavily prescribed drug with a very high perception of safety.

5. It made the risks very clear to consumers and the FDA. A single tablet of Zantac had more than 26,000 times the daily amount of NDMA recommended by the FDA.[4] This is when patients were being prescribed two tablets a day to treat an ulcer.[5]

6. On September 13, 2019, the FDA notified the public of the potential dangers posed by Ranitidine.[6] The news was enough for other companies to issue recalls[7] and for several other countries to halt sales of the drug entirely.

1 Teng Zeng & William A. Mitch, Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).
2 Valisure Citizen Petition to FDA ("Citizen Petition"), available at https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf.
3 *Id*.
4 *Id*.
5 Drug Record: Ranitidine, NATIONAL INSTITUTES OF HEALTH (updated July 1, 2019), https://livertox.nih.gov/Ranitidine.htm.
6 https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.
7 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg-due-elevated; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and

7. But still Sanofi would not issue a recall. It did not do so until October 18, 2019, after the potential risks were well publicized by the FDA and the media.

8. But Sanofi's recall is far from an adequate response. The problem is that Sanofi knew its drug posed a risk to consumers and it chose not to disclose that information. This is when safer alternatives existed, which without a doubt patients would have taken to avoid unnecessary risks to their health. But Sanofi put profits above the safety of its consumers and kept that information from them. Had consumers known that taking Zantac would expose them to unhealthy levels of the carcinogen NDMA, consumers including Plaintiffs and putative class members would not have purchased the drug. And Sanofi's failure to disclose this material information is a violation of New Jersey's laws.

PARTIES

9. Plaintiff Michelle Coggins is an individual who resides in Warminster, Pennsylvania.

10. Plaintiff Michelle Coggins began purchasing over-the-counter Zantac from on or about 2017 to on or about September 2019. Plaintiff Michelle Coggins took the medication almost daily, about twice a day.

11. Plaintiff Michelle Coggins purchased Zantac in the form of 150 mg tablets at CVS in Warminster, Pennsylvania.

12. Plaintiff Michelle Coggins spent approximately $324 on Zantac during the entire time she took the medication.

13. Plaintiff Sandra R. Weeks is an individual who resides in Winterville, North Carolina.

14. Plaintiff Sandra R. Weeks began purchasing over-the-counter Zantac from on or about 2018 to on or about September 2019. Plaintiff Sandra R. Weeks would take the medication twice a day, seven days a week.

15. Plaintiff Sandra R. Weeks purchased Zantac in the form of 150 mg

tablets at Sam's Club.

16. Plaintiff Sandra R. Weeks spent approximately $360 on Zantac during the entire time she took the medication.

17. If Plaintiffs had known that taking Zantac would expose them to unsafe levels of NDMA, she would not have purchased or used the drug.

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

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

20. 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.

21. 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.

22. 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. It manufactured and distributed the drug in the United States during that period.

23. Plaintiffs are unaware of the true names, capacities, relationship and extent of participation in the conduct alleged herein, of the Defendants sued

herein as DOES 1 through 20 but is informed and believes that said Defendants are legally responsible for the wrongful conduct alleged herein and therefore sues these Defendants by fictitious names. Plaintiffs will amend this complaint to allege the true names and capacities of DOE Defendants when ascertained.

JURISDICTION AND VENUE

24. This Court has jurisdiction over Plaintiffs' claims under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds $5 million exclusive of interest and costs. Some Class Members and Defendants are citizens of different states. There are at least 100 putative Class Members throughout the State of California.

25. 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.

26. 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.

27. Plaintiffs are informed and believe that each Defendant acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan or policy in all respects pertinent hereto, and the acts of each Defendant are legally attributable to the other Defendants.

FACTUAL ALLEGATIONS

28. Sanofi is a French multinational pharmaceutical company and as of 2013, the world's fifth largest by prescription sales.

29. Sanofi makes the drug Ranitidine, also known by its brand name as Zantac.

30. Zantac is available over the counter and is commonly used to treat heartburn and ulcers. The drug is also prescribed by doctors for more serious conditions requiring daily doses over a period of several weeks.

31. The drug has been on the market since 1981 and was prescribed to millions of people because it was marketed as a safe and effective drug. Until recently, it was one of the best-selling drugs on the market.

32. In addition to Zantac, there are several other safer alternative drugs on the market like Prilosec, Pepcid, Nexium, Prevacid, and Tagamet used to treat heartburn symptoms.

A. It Becomes Public that Zantac Contains the Carcinogen NDMA

33. Valisure is an online pharmacy that sold Zantac and its generic version, known as Ranitidine. It conducts its own testing on every batch of medication it sells.[8] During its testing, it discovered that Zantac contained unsafe levels of the carcinogen N-nitrosodimethylamine (NDMA). It notified the FDA of its initial finding in June 2019.

34. The FDA has an established daily limit of 96 nanograms of NDMA. Valisure had detected in excess of 3,000,000 nanograms of NDMA per tablet of Ranitidine. The results are alarming because often consumers are prescribed as much as two daily tablets for several weeks.

35. On September 9, 2019, Valisure submitted a citizen petition to the FDA to recall and suspend all sales of the drug Ranitidine from the U.S. market, including Zantac.[9]

36. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in Ranitidine medications, including Zantac. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a

8 https://www.valisure.com/
9 https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf

substance that could cause cancer) based on results from laboratory tests." This was an initial warning that put consumers and doctors on alert of the possible link between Ranitidine and NDMA.

37. On September 23, 2019, a pharmaceutical manufacturer that also sold Ranitidine issued a recall of the drug. The company known as Sandoz Inc. confirmed that NDMA had also been found in levels above the limit established by the FDA. It recalled all batches of Sandoz Ranitidine Hydrochloride Capsules.

38. On September 25, 2019, another pharmaceutical manufacturer that also sold Ranitidine issued a recall of the drug. The company known as Apotex Corp. recalled all batches of the drug it sold, which were mainly distributed at Rite Aid, Walmart, and Walgreens.

39. In a move that made public headlines, the retailer CVS then pulled all brands of Ranitidine off its shelves including Zantac. Walgreens followed suit and so did Rite Aid shortly thereafter.

40. By this time, several other countries had also pulled the drug from the market. Germany, Switzerland, and Austria all initiated recalls, and Finland also pulled the drug from its pharmacies. Singapore also suspended the sale and supply of several brands of Ranitidine, and several other countries stopped further distribution.

41. Still Sanofi refused to issue a recall. It was not until October 18, 2019 that Sanofi finally issued a recall of Zantac.

B. The Dangers of the Carcinogen NDMA

42. The dangers of N-Nitrosodimethylamine (NDMA) have been known for years, and the Centers for Disease Control and Prevention (CDC) has stated publicly that NDMA is very harmful to humans.[10]

[10] https://www.atsdr.cdc.gov/toxprofiles/tp141-c1.pdf

43. Testing done on animals showed that food, water, and air with high levels of NDMA caused serious liver disease. When rats, mice, hamsters, and other animals ate food, drank water, or breathed air containing lower levels of NDMA for periods more than several weeks, liver cancer and lung cancer as well as non-cancerous liver damage occurred.

44. The high level short-term and low-level long-term exposures that caused non-cancerous liver damage and/or cancer in animals also usually resulted in internal bleeding and death. Based on these studies, it is reasonable to expect that exposure to NDMA by eating, drinking, or breathing could cause cancer in humans. Mice that were fed NDMA during pregnancy had offspring that were born dead or died shortly after birth.

45. Numerous studies have confirmed the dangers of NDMA, and the FDA has set a strict daily limit of 96 nanograms in pharmaceutical products.

46. Because of the real dangers of NDMA, this limit is strictly adhered to and a multitude of medications have been recalled including the popular drug Valsartan. Taken to treat high blood pressure, Valsartan was recalled for having as much as 17,000 nanograms of NDMA in a single pill.

47. In Zantac, tests have found as much as 2,511,469 nanograms of NDMA in 150 mg Zantac tablets. It poses the greatest risk of any drug thus far recalled, with the information and means available to Sanofi, customers should have been informed of these dangers before ever buying the drug.

C. Sanofi Failed to Disclose the Risks of Taking Zantac

48. Sanofi knew or should have known that Zantac had unsafe levels of NDMA, and that information should have been disclosed to consumers.

49. Since at least 2003, it was proposed that elevated levels of NDMA in drinking water produced by American wastewater treatment plants may be

associated with the drug ranitidine.[11]

50. In 2010, it was found that Ranitidine showed the strongest potential to form NDMA in drinking water during the chloramine disinfection process.[12] A similar study also found that Ranitidine was a major precursor of NDMA in drinking water being treated with a chloramine disinfectant.[13] This was further supported by another study in 2014 that found that Ranitidine was a potent NDMA precursor, also during Chloramination.[14]

51. In 2016, a study conducted by Stanford University found that healthy individuals that took Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 40,000 nanograms) in the proceeding 24 hours after ingestion.[15] The results were exponentially higher than the 96 nanograms allowed by the FDA. And the implications of the test could be significantly worse because NDMA is known to be heavily absorbed by the body instead of being excreted into urine.[16]

52. The study stated as much, "While urinary N-nitrosamine concentrations may more directly reflect systemic exposure, it is important to note that such estimates are conservative. Actual systemic NDMA exposure is likely much higher than that eliminated in urine, as previous studies have indicated a

[11] Mitch, W.A., Sharp, J.O., Trussell, R.R., Valentine, R.L., Alvarez-Cohen, L. and Sedlak, D.L. (2003). N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review. Environmental Engineering Science. Vol. 20, p. 5 (https://superfund.berkeley.edu/pdf/231.pdf).
[12] 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)
[13] Le Roux, J., Gallard, H., Croue, J., Papot, S., Deborde, M. (2012). NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism. Environ. Sci. Technol. Vol. 46, p. 20 (https://pubs.acs.org/doi/10.1021/es3023094).

[14] 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).
[15] Teng Zeng & William A. Mitch, Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).
[16] Spiegelhalder, B., Eisenbrand, G., Preussmann, R. (1982). Urinary excretion of N-nitrosamines in rats and humans. IARC Sci Publ. Vol. 41 p. 443-449 (https://www.ncbi.nlm.nih.gov/pubmed/7141551).

high metabolic conversion rate of NDMA (i.e. >99.9%) and therefore its low renal clearance (i.e. only ~0.05% excreted in urine)."

53. This study in particular carries tremendous weight because unlike previous studies, scientists were studying the effects of Ranitidine in the body, and were finding a link to NDMA. And scientists were finding that in comparison to people actually suffering from bladder cancer, individuals in the study had in some instances more NDMA in their urine.

54. None of the information that was steadily building throughout these studies was ever disclosed by Sanofi on its product label.

55. This was despite the fact that Sanofi was required by law to submit an annual report to the FDA containing such information. Sanofi was required to submit a report containing a brief summary of significant new information affecting the safety, effectiveness, or labeling of the drug product. *See* 21 C.F.R. § 314.81(b)(2). It is accompanied by copies of unpublished reports and summaries of published reports of new toxicological findings concerning the ingredients in the drug product. *See* 21 C.F.R. § 314.81(b)(2)(v).

56. Defendants did not abide by these regulations and did not disclose to the FDA the alarming results connecting Ranitidine and NDMA, as these studies certainly affected the safety and labeling of Zantac.

CLASS ACTION ALLEGATIONS

57. Plaintiffs bring this action in their individual capacity and as a class action pursuant to Federal Rule of Civil Procedure 23 on behalf of the following proposed nationwide class:

> **Nationwide Class**: All persons who purchased over-the-counter Zantac in the United States.

58. Excluded from the Class are Defendants, as well as their officers, employees, agents or affiliates, and any judge who presides over this action, as

well as all past and present employees, officers and directors of Defendants. Plaintiffs reserve the right to expand, limit, modify, or amend the Class and definitions, including the addition of one or more subclasses, in connection with their motion for class certification, or at any other time, based upon, *inter alia*, changing circumstances and/or new facts obtained during discovery.

59. The Class meets the requirements of Federal Rules of Civil Procedure 23(a) and 23(b) for all the following reasons.

60. **Numerosity** – Although the exact number of Class members is uncertain, and can only be ascertained through appropriate discovery, the number is great enough such that joinder is impracticable. The disposition of the claims of these Class members in a single action will provide substantial benefits to all parties and the Court. Information concerning the exact size of the putative class is within the possession of Defendants. The parties will be able to identify each member of the Class after Defendants' document production and/or related discovery.

61. **Commonality** – Common questions of fact and law exist as to all Class members and predominate over any questions that affect only individual Class members, including by example only and without limitation, the following:

a. Whether the Zantac sold by Defendants exposed Plaintiffs and Class members to unsafe levels of the carcinogen NDMA;
b. Whether Defendants knew or should have known that Zantac exposes consumers 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.

62. **Typicality –** All of Plaintiffs' claims are typical of the claims of the proposed Class they seek to represent in that: Plaintiffs and Class members were misled into purchasing Zantac because Defendants failed to disclose that Zantac has unsafe levels of the carcinogen NDMA. If Defendants had disclosed this information, Plaintiffs and Class members would not have purchased the drug; Plaintiffs' claims arise from the same practice or course of conduct that forms the basis of the Class claims; Plaintiffs' claims are based upon the same legal and

remedial theories as the proposed Class and involve similar factual circumstances; there is no antagonism between the interests of Plaintiffs and absent Class members; the injuries that Plaintiffs suffered are similar to the injuries that Class members have suffered.

63. **Adequacy** – Plaintiffs will fairly and adequately represent the Class in that: (1) there is no conflict between Plaintiffs' claims and those of other Class members; (2) Plaintiffs have retained counsel who are skilled and experienced in class actions and who will vigorously prosecute this litigation; (3) Plaintiffs' claims are typical of the claims of Class members.

64. **Predominance –** The proposed action meets the requirements of Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact common to the Class predominate over any questions which may affect only individual Class members.

65. **Superiority** – A class action is superior to all other methods available for the fair and efficient adjudication of this controversy. Because the amount of each individual class member's claim is small relative to the complexity of the litigation, and given Zantac's financial resources, no class member would be likely to pursue legal redress individually for the violations detailed herein. A class action would also streamline the determination of common claims or issues in this case. Conversely, individual suits would create the potential for inconsistent or contradictory rulings. By contrast, a class action presents fewer management difficulties, allows claims to be heard which would otherwise go unheard, and allows comprehensive supervision by a single court.

66. Injunctive Relief - Class certification is also appropriate under Rule 23(b)(2) because Zantac acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the class.

FIRST CAUSE OF ACTION
VIOLATION OF NEW JERSEY CONSUMER FRAUD ACT
N.J.S.A 56:8-1 et seq.
(On Behalf of the Nationwide Class)

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

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

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

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

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

72. 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.

73. 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 . . . ."

74. As described in this Complaint, Defendants conduct constitutes

"deceptive," "unfair," and "unconscionable" acts or practices in violation of the Consumer Fraud Act.

75. Defendants' practices violated the Act for, among other things, concealing from Plaintiffs and Class members the material fact that Zantac was defective, and as such, was not of merchantable quality. Defendants also engaged in unconscionable commercial practices in failing to disclose material information discussed above regarding the relationship between Zantac and NDMA.

76. Defendants deliberately omitted and failed to disclose material facts to Plaintiffs and Class members regarding the defects in Zantac.

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

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

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

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

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

82. 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 Plaintiffs and Class members about this defect despite having a duty to do so.

83. 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.

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

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

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

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

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

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

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

91. Defendants' concealment of the defects in Zantac was material to Plaintiffs and Class members.

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

93. As a direct and proximate result of Defendants' violations of the Consumer Fraud Act, Plaintiffs and Class members have suffered injury-in-fact

and actual damages.

94. Plaintiffs 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 Plaintiffs and Class members.

95. Because Defendants' unconscionable conduct caused injury to Plaintiffs and Class members, Plaintiffs 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.

SECOND CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(On Behalf of the Nationwide Class)

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

97. Plaintiffs bring this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

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

99. 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.

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

101. 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 Defendants' material representations.

102. 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.

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

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

105. 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.

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

107. 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.

108. Because of Defendants' concealment and suppression of facts,

Plaintiffs and Class members sustained damage because they would not have purchased or consumed Zantac but for Defendants' actions.

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

110. 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 themselves. Plaintiffs and Class members request an assessment of punitive damages in an amount sufficient to deter such conduct in the future.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES
UNIFORM COMMERICAL CODE, N.J.S. 12A:1-101 et seq.
(On Behalf of the Nationwide Class)

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

112. This claim is brought against all Defendants by Plaintiffs on behalf of themselves and the Nationwide Class.

113. 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 Plaintiffs and Defendants.

114. 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. 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.

115. 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 Plaintiffs and Class members. Plaintiffs and Class members were therefore induced to purchase Zantac under false or fraudulent pretenses.

116. Because of 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 Defendants.

117. Defendants have been provided notice of these issues by (among other things) communications from the FDA, scientific and news articles, and this Complaint.

118. As a direct and proximate result of 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated, requests that the Court enter judgment against Defendants as follows:

A. An order certifying this action as a class action under Federal Rule of Civil Procedure 23, defining the Class as requested herein, appointing the undersigned as Class Counsel, and finding that Plaintiffs are proper representatives of the Class herein;

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, statutory, punitive, and treble damages;

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

G. 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;

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

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

J. Such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs, on behalf of themselves and the Class, hereby demand a trial by jury pursuant to Federal Rule of Civil Procedure 38(b) on all claims so triable.

Respectfully submitted,

Dated: November 11, 2019

/s/ Bradley K. King
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* Pro Hac Vice Application Forthcoming