UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANA VIOLA, on behalf of herself and all others similarly situated, Plaintiff, v. PFIZER INC., Defendant.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Dana Viola ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendant Pfizer Inc. ("Pfizer" or "Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendant's manufacturing, distribution, and sale of ranitidine-based over-the-counter medications under the brand name Zantac that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity.

2. Zantac is an over-the-counter medication that contains ranitidine, which decreases the amount of acid created by the stomach. Over-the-counter Zantac is used for the treatment of heartburn associated with indigestion and sour stomach. However, Defendant's manufacturing process has caused Zantac to contain dangerously high levels of NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens."

While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine medications, including Zantac.[1] The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."[2]

5. Several pharmaceutical manufacturers have issued recalls or halted the sale of their ranitidine-containing medications. Pharmacies such as Walgreens, Rite Aid, and CVS have also ceased selling ranitidine-containing medications.

6. On October 18, 2019, Sanofi-Aventis U.S. LLC, who currently holds the new drug application ("NDA") for over-the-counter Zantac, issued a voluntary recall of Zantac "due to inconsistencies in preliminary test results" of the active ingredient in Zantac.[3]

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[1] Food & Drug Admin., Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[2] Food & Drug Admin., 10/2/19: UPDATE – FDA Provides Update on Testing of Ranitidine for NDMA Impurities (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[3] Jen Christensen, *Sanofi Recalls Popular Heartburn Medication Zantac OTC*, CNN, Oct. 18, 2019, https://www.cnn.com/2019/10/18/health/zantac-otc-recall/index.html (last visited Oct. 22, 2019).

A. Zantac Is Marketed As Safe

7. Defendant has always marketed Zantac as a safe and effective product, despite evidence to the contrary.

8. Zantac is one of the most successful drugs in history. It reached $1 billion in sales in December 1986.[4]

9. Pfizer manufactured and maintained control over Zantac from 2000 through December 2006. Pfizer inherited the rights to Zantac when Pfizer acquired Warner-Lambert, Inc.

10. Pfizer was the original NDA holder for over-the-counter Zantac, and maintained control over the NDA through 2006. It was Pfizer who procured FDA approval for an over-the-counter version of Zantac in the United States.[5]

11. On the original label of Zantac, Pfizer noted Zantac "relieves heartburn" and "prevents heartburn."[6] The label did not represent NDMA as an ingredient in the medication, and did not provide any disclosures as to NDMA's cancer-causing properties.

B. Zantac Contains Dangerous Levels Of NDMA

12. While Defendant represented that its Zantac formulation was safe for use, Zantac contains dangerously high levels of NDMA, rendering the product dangerous and unfit for human consumption. NDMA would not be present if the medication were properly synthesized.

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

[5] Manas Mishra & Michael Erman, *Timeline: Popular Heartburn Medicine Zantac Pulled off Store Shelves*, REUTERS (Oct. 2, 2019), https://www.reuters.com/article/us-health-fda-heartburn-timeline/timeline-popular-heartburn-medicine-zantac-pulled-off-store-shelves-idUSKBN1WH2K7 (last visited Nov. 25, 2019).

[6] OVER-THE-COUNTER (OTC) ZANTAC 150 (RANITIDINE TABLETS 150 MG), https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21698lbl.pdf (last visited Nov. 25, 2019).

As noted in paragraph 4, *supra*, the FDA has found unacceptable levels of NDMA in samples of ranitidine.

13. The Medicines and Healthcare Products Regulatory Agency of the United Kingdom also issued an alert regarding Zantac, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA."[7] "The MHPRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue."[8]

14. The FDA has established a "permissible daily intake limit for … NDMA of 96 [nanograms]."[9] But Zantac has an NDMA content of between 2.5-2.8 million nanograms *per tablet*, according to testing by Valisure, an FDA-registered online pharmacy.[10]

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	**18M498M**	**2,511,469**
Zantac (mint), Brand OTC	**18H546**	**2,834,798**
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

15. Similarly, the FDA found Zantac to contain NDMA as high as 2.38 parts per

[7] Medicine and Healthcare Regulatory Agency, Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls all Unexpired Stock (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.
[8] *Id*.
[9] VALISURE, VALISURE CITIZEN PETITION ON RANITIDINE 1 (2019), https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (last visited Oct. 22, 2019) (hereinafter "VALISURE PETITION").
[10] *Id*. at 6.

million, which is well above the FDA limit of 0.32 parts per million.[11]

16. Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[12]

C. Plaintiff Was Harmed By Purchasing And Consuming Defective Zantac Manufactured By Defendant

17. Plaintiff and the Class were injured by the full purchase price of their Zantac medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendant's conduct.

18. Plaintiff brings this action on behalf of herself, the Class, and the New Jersey Subclass (defined below) for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 *et seq.*, (iv) unjust enrichment, (v) fraudulent concealment, (vi) fraud, and (vii) conversion.

PARTIES

19. Plaintiff Dana Viola is a citizen of New Jersey who resides in Tenafly, New Jersey. Ms. Viola began purchasing and consuming Zantac in 2000, at which time the product

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[11] Food & Drug Admin., Laboratory Tests | Ranitidine (Nov. 1, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (last visited Nov. 20, 2019).

[12] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

was manufactured by Defendant, and continued to purchase and consume Zantac throughout Defendant's ownership and control of the NDA for over-the-counter Zantac medication. Ms. Viola regularly purchased and consumed Zantac from 2000-2016. Ms. Viola originally learned about the Zantac defect when she saw news stories relating to the recall of Zantac. When purchasing Zantac from Defendant, Ms. Viola reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Ms. Viola relied on these representations and warranties in deciding to purchase Zantac from Defendant, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased Zantac from Defendant if she had known that they were not, in fact, properly manufactured and free from defects. Ms. Viola also understood that each purchase involved a direct transaction between herself and Pfizer because her medication came with packaging and other materials prepared by Pfizer, including representations and warranties that her medications were properly manufactured and free from defects.

20. Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer maintained control over the NDA from 2000-2006. It was Pfizer who procured FDA approval for an over-the-counter version of Zantac in the United States.[13] Pfizer conducts substantial business in the United States, and specifically in the State of New Jersey. Pfizer has been engaged in the

[13] Manas Mishra & Michael Erman, *Timeline: Popular Heartburn Medicine Zantac Pulled off Store Shelves*, REUTERS (Oct. 2, 2019), https://www.reuters.com/article/us-health-fda-heartburn-timeline/timeline-popular-heartburn-medicine-zantac-pulled-off-store-shelves-idUSKBN1WH2K7 (last visited Nov. 25, 2019).

manufacturing, distribution, and sale of defective Zantac in the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

21. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant has its principal place of business in this District.

CLASS ALLEGATIONS

23. Plaintiff seeks to represent a class defined as all persons in the United States who purchased Zantac (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

24. Plaintiff also seeks to represent a subclass of all Class members who purchased Zantac in New Jersey (the "New Jersey Subclass").

25. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and New Jersey Subclass may be expanded or

narrowed by amendment or amended complaint.

26. **Numerosity.** The members of the Class and New Jersey Subclass are geographically dispersed throughout the United States and the State of New Jersey and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class and tens of thousands of members in the New Jersey Subclass. Although the precise number of Class members is unknown to Plaintiff, the true number of Class and New Jersey Subclass members is known by Defendant and may be determined through discovery. Class and New Jersey Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

27. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and New Jersey Subclass and predominate over any questions affecting only individual Class and New Jersey Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Zantac medication manufactured by Defendant contains dangerously high levels of NDMA, thereby breaching the express and implied warranties made by Defendant and making Zantac unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendant knew or should have known that Zantac contained elevated levels of NDMA prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant has unlawfully converted money from Plaintiff and the Class and New Jersey Subclass;

(d) whether Defendant is liable to Plaintiff and the Class and New Jersey Subclass for unjust enrichment;

(e) whether Defendant is liable to Plaintiff and the Class and New Jersey Subclass for fraudulent concealment;

(f) whether Defendant is liable to Plaintiff and the New Jersey Subclass for violations of New Jersey's consumer-protection laws;

(g) whether Plaintiff and the Class and New Jersey Subclass have sustained monetary loss and the proper measure of that loss;

(h) whether Plaintiff and the Class and New Jersey Subclass are entitled to declaratory and injunctive relief;

(i) whether Plaintiff and the Class and New Jersey Subclass are entitled to restitution and disgorgement from Defendant; and

(j) whether the marketing, advertising, packaging, labeling, and other promotional materials for Zantac are deceptive.

28. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New Jersey Subclass in that Defendant mass marketed and sold defective Zantac to consumers throughout the United States. This defect was present in all of the Zantac manufactured by Defendant. Therefore, Defendant breached its express and implied warranties to Plaintiff and Class and New Jersey Subclass members by manufacturing, distributing, and selling the defective Zantac. Plaintiff's claims are typical in that she and the Class were uniformly harmed in purchasing and consuming the defective Zantac. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as it deceived each member of the Class and New Jersey Subclass. Further, there are no defenses available to

Defendant that are unique to Plaintiff.

29. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and New Jersey Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and New Jersey Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and New Jersey Subclass.

30. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and New Jersey Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class and New Jersey Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and New Jersey Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

31. In the alternative, the Class and New Jersey Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and New Jersey Subclass members would create a risk of inconsistent or varying adjudications with respect to individual

Class and New Jersey Subclass members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class and New Jersey Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and New Jersey Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class and New Jersey Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New Jersey Subclass as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Class And New Jersey Subclass)

32. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

33. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New Jersey Subclass against Defendant.

34. Plaintiff, and each member of the Class and New Jersey Subclass, formed a contract with Defendant at the time Plaintiff and the other Class and New Jersey Subclass members purchased the defective Zantac. The terms of the contract include the promises and affirmations of fact made by Defendant on Zantac's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as NDMA. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract

between Plaintiff and the members of the Class and New Jersey Subclass and Defendant.

35. Plaintiff relied on the express warranty that her Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and New Jersey Subclass and Defendant.

36. Defendant purports, through its advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities such as NDMA.

37. Plaintiff and the Class and New Jersey Subclass performed all conditions precedent to Defendant's liability under this contract when they purchased the defective medication.

38. Defendant breached express warranties about the defective Zantac and its qualities because Defendant's statements about the defective Zantac were false and the defective Zantac does not conform to Defendant's affirmations and promises described above.

39. Plaintiff and each of the members of the Class and New Jersey Subclass would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained elevated levels of NDMA.

40. As a result of Defendant's breaches of express warranty, Plaintiff and each of the members of the Class and New Jersey Subclass have been damaged in the amount of the purchase price of Zantac and any consequential damages resulting from the purchases.

41. On December 30, 2019, prior to filing this action, Defendant was served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendant a letter advising them that they breached an express warranty and

demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit A**.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And New Jersey Subclass)

42. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

43. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New Jersey Subclass against Defendant.

44. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that Zantac (i) would not contain elevated levels of NDMA and (ii) is generally recognized as safe for human consumption.

45. Defendant breached the warranty implied in the contract for the sale of the defective Zantac because it could not pass without objection in the trade under the contract description, the Zantac was not of fair or average quality within the description, and the Zantac was unfit for its intended and ordinary purpose because the Zantac manufactured by Defendant was defective in that it contained elevated levels of carcinogenic and liver toxic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and New Jersey Subclass members did not receive the goods as impliedly warranted by Defendant to be merchantable.

46. Plaintiff and Class and New Jersey Subclass members purchased Zantac in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

47. The Zantac was not altered by Plaintiff or Class and New Jersey Subclass members.

48. The Zantac was defective when it left the exclusive control of Defendant.

49. Defendant knew that the Zantac would be purchased and used without additional testing by Plaintiff and Class and New Jersey Subclass members.

50. The defective Zantac was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and New Jersey Subclass members did not receive the goods as warranted.

51. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff and Class and New Jersey Subclass members have been injured and harmed because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and is not generally recognized as safe for human consumption; and (b) Zantac does not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

COUNT III
Violation Of New Jersey's Consumer Fraud Act
(On Behalf Of The New Jersey Subclass)

52. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

53. Plaintiff brings this claim individually and on behalf of the members of the proposed New Jersey Subclass against Defendant.

54. The New Jersey Consumer Fraud Act ("NJCFA") prohibits "[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 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, is declared to be an unlawful practice… ." N.J.S.A. § 56:8-2.

55. Plaintiff Viola and members of the New Jersey Subclass are consumers who purchased Zantac for personal, family, or household use.

56. In violation of the NJCFA, Defendant employed unconscionable commercial practices, deception, fraud, and/or false pretense by providing Zantac that is contaminated with NDMA and presents an undisclosed safety risk to consumers and users of Zantac. Further, Defendant failed to disclose the NDMA contamination and corresponding safety risk in violation of the NJCFA.

57. Defendant's fraudulent omissions were material to Plaintiff and members of the New Jersey Subclass. When Plaintiff and members of the New Jersey Subclass purchased Zantac, they reasonably relied on the expectation that Zantac (i) would not contain dangerously high levels of NDMA, and (ii) was generally recognized as safe for human consumption.

58. Had Defendant disclosed that Zantac contained dangerously high levels of NDMA and was unsafe for human consumption, Plaintiff and members of the New Jersey Subclass would not have purchased Zantac or would they have paid less for it.

59. Defendant knowingly concealed, suppressed and/or omitted the presence of the NDMA contamination and safety risk in Zantac at the time of sale and at all relevant times thereafter.

60. Defendant owed a duty to disclose the NDMA contamination and its

corresponding safety risk to Plaintiff and members of the New Jersey Subclass because Defendant possessed superior and exclusive knowledge regarding the NDMA contamination and the risks associated with the consumption of NDMA.

61. Defendant knew, or should have known, that the NDMA contamination in Zantac made Zantac unsafe for human consumption. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[14] Likewise, in 2004, a study found the use of Zantac to be "related to the risk of bladder cancer."[15] During that time, Plaintiff and Class and New Jersey Subclass members were using Zantac without knowing it contained dangerous levels of NDMA.

62. As a direct and proximate result of Defendant's wrongful conduct in violation of the NJCFA, Plaintiff and members of the New Jersey Subclass have suffered and continue to suffer ascertainable loss in the form of monies paid for defective, worthless Zantac medications.

63. On behalf of herself and other members of the New Jersey Subclass, Plaintiff seeks to recover actual damages, treble damages, costs, attorneys' fees, and other damages to be determined at trial. *See* N.J.S.A. § 56:8-19.

64. On December 30, 2019, prior to filing this action, Defendant was served with a pre-suit notice letter advising Defendant of its violation of the NJCFA and demanding full restitution. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit A**.

[14] VALISURE PETITION at 4-5.
[15] Dominque S. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 250, 252 (2004) https://pdfs.semanticscholar.org/3eeb/c399404a2b100d90c6698bd4fc73a748864e.pdf.

COUNT IV
Unjust Enrichment
(On Behalf Of The Class And New Jersey Subclass)

65. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

66. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New Jersey Subclass against Defendant.

67. Plaintiff and the Class and New Jersey Subclass conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Zantac.

68. Defendant voluntarily accepted and retained this benefit.

69. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT V
Fraudulent Concealment
(On Behalf Of The Class and New Jersey Subclass)

70. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

71. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New Jersey Subclass against Defendant.

72. Defendant had a duty to disclose material facts to Plaintiff and the Class and New Jersey Subclass given their relationship as contracting parties and intended users of Zantac. Defendant also had a duty to disclose material facts to Plaintiff and the Class and New Jersey Subclass, namely that they were in fact manufacturing, distributing, and selling harmful Zantac unfit for human consumption, because Defendant had superior knowledge such that the

transactions without the disclosure were rendered inherently unfair.

73. Defendant possessed knowledge of these material facts. In 2003, it was "proposed that elevated levels of NDMA in drinking water…may be associated with the drug ranitidine."[16] Likewise, in 2004, a study found the use of Zantac to be "related to the risk of bladder cancer."[17] During that time, Plaintiff and Class and New Jersey Subclass members were using Zantac without knowing it contained dangerous levels of NDMA.

74. Defendant failed to discharge their duty to disclose these materials facts.

75. In so failing to disclose these material facts to Plaintiff and the Class and New Jersey Subclass, Defendant intended to hide from Plaintiff and the Class and New Jersey Subclass that they were purchasing and consuming Zantac with harmful defects that was unfit for human use, and thus acted with scienter and/or an intent to defraud.

76. Plaintiff and the Class and New Jersey Subclass reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the defective Zantac manufactured and sold by Defendant had they known it contained unsafe levels of NDMA.

77. As a direct and proximate cause of Defendant's fraudulent concealment, Plaintiff and the Class and New Jersey Subclass suffered damages in the amount of monies paid for the defective Zantac.

78. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

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[16] VALISURE PETITION at 4-5.

[17] Dominque S. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 250, 252 (2004) https://pdfs.semanticscholar.org/3eeb/c399404a2b100d90c6698bd4fc73a748864e.pdf.

COUNT VI
Fraud
(On Behalf Of The Class and New Jersey Subclass)

79. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

80. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New Jersey Subclass against Defendant.

81. As discussed above, Defendant provided Plaintiff and Class and New Jersey Subclass members with materially false or misleading information about the Zantac manufactured by Defendant. Specifically, Defendant marketed Zantac as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendant's Zantac medications contained elevated levels of NDMA.

82. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class and New Jersey Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and New Jersey Subclass members to purchase defective Zantac.

83. Defendant knew that Zantac was contaminated with this harmful impurity, but continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[18] Likewise, in 2004, a study found the use of Zantac to be "related to the risk of bladder cancer."[19] During that time, Plaintiff and Class and New Jersey Subclass members were using the medication without

[18] VALISURE PETITION at 4-5.
[19] Dominque S. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 250, 252 (2004) https://pdfs.semanticscholar.org/3eeb/c399404a2b100d90c6698bd4fc73a748864e.pdf.

knowing it contained dangerous levels of NDMA.

84. The fraudulent actions of Defendant caused damage to Plaintiff and Class and New Jersey Subclass members, who are entitled to damages and other legal and equitable relief as a result.

85. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VII
Conversion
(On Behalf Of The Class And New Jersey Subclass)

86. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

87. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New Jersey Subclass against Defendant.

88. Plaintiff and the Class and New Jersey Subclass have an ownership right to the monies paid for the defective Zantac manufactured by Defendant.

89. Defendant has wrongly asserted dominion over the payments illegally diverted to them for the defective Zantac. Defendant has done so every time that Plaintiff and the Class and New Jersey Subclass bought Zantac over the counter.

90. As a direct and proximate cause of Defendant's conversion, Plaintiff and the Class and New Jersey Subclass suffered damages in the amount of the payments made for each time they bought Zantac over the counter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

A. For an order certifying the nationwide Class and the New Jersey Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and New Jersey Subclass and Plaintiff's attorneys as Class Counsel;

B. For an order declaring the Defendant's conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the nationwide Class, and the New Jersey Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief; and

G. For an order awarding Plaintiff and the Class and New Jersey Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: January 2, 2020

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Andrew J. Obergfell*
Andrew J. Obergfell

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EXHIBIT A

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December 30, 2019

Via Certified Mail – Return Receipt Requested

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607;
New Jersey Consumer Fraud Act §§ N.J.S.A. §§ 56:8-1 et seq.;
And all other relevant state and local laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Pfizer Inc. ("Pfizer") pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws – related to our client, Dana Viola, and a class of all similarly situated purchasers (the "Class") of defective Zantac manufactured by Pfizer.

Our client purchased Zantac, a medication containing the active-ingredient ranitidine, manufactured by Pfizer, in New Jersey. Our client's Zantac was defective in that it contained elevated levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. On September 13, 2019, the U.S. Food & Drug Administration ("FDA") announced the presence of NDMA in ranitidine-containing medications, including Zantac. The FDA has since found unacceptable levels of NDMA in samples of ranitidine. In short, the Zantac medications that our client and the Class purchased are worthless, as they contain NDMA, rendering them unusable and unfit for human consumption. Pfizer violated express and implied warranties made to our client and the Class regarding the quality and safety of the Zantac they purchased. *See* U.C.C. §§ 2-313, 2-314.

Additionally, this letter also serves as notice of violation of the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1 *et seq.* ("NJCFA"), and all other relevant state and local laws. As a result of Pfizer's violation of the NJCFA, Ms. Viola sustained injury.

On behalf of our client and the Class, we hereby demand that Pfizer immediately make full restitution to all purchasers of the defective Zantac of all purchase money obtained from sales thereof.

We also demand that Pfizer preserve all documents and other evidence which refers or relates to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Pfizer's Zantac;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of Zantac manufactured by Pfizer;

3. All tests of Zantac manufactured by Pfizer;

4. All documents concerning the pricing, advertising, marketing, and/or sale of Zantac manufactured by Pfizer;

5. All communications with customers involving complaints or comments concerning the Zantac manufactured by Pfizer;

6. All documents concerning communications with any retailer involved in the marketing or sale of Zantac manufactured by Pfizer;

7. All documents concerning communications with federal or state regulators; and

8. All documents concerning the total revenue derived from sales of Zantac.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Andrew J. Obergfell

Andrew J. Obergfell