UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Yesenia Melillo, individually and on behalf of all others similarly situated, Plaintiff, -against- Sanofi-Aventis U.S. LLC; Sanofi US Services Inc. and Chattem, Inc., Defendants.	:	Case No.

CLASS ACTION COMPLAINT

Plaintiff Yesenia Melillo, by her attorneys, alleges the following:

NATURE OF THE ACTION

1. The action arises from the recent public revelation that the popular heartburn drug ranitidine, which is sold both over-the-counter and by prescription under the brand-name Zantac as well as under generic and store brands, has exposed users to a known cancer-causing agent—N-Nitrosodimethylamine ("NDMA"). The U.S. Food and Drug Administration ("FDA") found NDMA in both Zantac and generic ranitidine, and has suggested that people who purchase it over-the–counter consider purchasing another product. Zantac has been recalled in Canada and Europe.

2. National retailers, such as Wal-Mart, CVS, Walgreens and Rite Aid, have suspended their sales of ranitidine including the Zantac branded product, and removed over-the-counter ranitidine from their store shelves.

3. Defendants sold and distributed Zantac branded ranitidine for purchase from at least January 2017 to the present. Plaintiff and other consumers in the state of New York purchased Zantac in the state of New York within the past three years.

4. Although Defendants knew or should have known that consumption of Zantac would expose the Plaintiff and other users to unacceptable levels of NDMA, they sold and distributed Zantac in a false, deceptive and misleading manner by failing to disclose a material fact – that Zantac use would expose consumers to cancer-causing NDMA – in violation of New York's General Business Law § 349 ("GBL § 349").

5. On account of Defendants' conduct in violation of GBL § 349, Plaintiff and the members of the class suffered actual injury when they purchased Zantac and did not receive the full value for their purchases.

JURISDICTION AND VENUE

6. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. § 1332(d). The amount in controversy in this class action exceeds $5,000,000, exclusive of interest and costs, and there are numerous Class members who are citizens of states other than Defendant's states of citizenship.

7. This Court has personal jurisdiction over Defendants in this matter. Defendants' sales of ranitidine giving rise to this action occurred in the state of New York. Defendants have been afforded due process because they have, at all times relevant to this matter, individually or through their agents, subsidiaries, officers and/or representatives, operated, conducted, engaged in and carried on a business venture in this state and/or maintained an office or agency in this state, and/or marketed, advertised, distributed and/or sold products, committed a statutory violation within this state related to the allegations made herein, and caused injuries to Plaintiff

and Class Members, which arose out of the acts and omissions that occurred in the state of New York, during the relevant time period, at which time Defendants were engaged in business activities in the state of New York.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District and because Defendants transact business and/or have agents within this District and have intentionally availed themselves of the laws and markets within this district.

PARTIES

9. Plaintiff Yesenia Melillo is a citizen of the state of New York and resides in this judicial district. Plaintiff purchased over-the-counter Zantac 150mg tablets in the state of New York.

10. Defendant Sanofi-Aventis U.S. LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

11. Defendant Sanofi US Services Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is registered to do business in the state of New York.

12. Defendant Chattem, Inc. is a corporation organized and existing under the laws of Tennessee with a principal place of business at 1715 West 38th Street, Chattanooga, Tennessee 37409.

13. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") are each wholly owned subsidiaries of Sanofi, located in Paris, France. Together, the Sanofi Defendants owned the rights to manufacture,

distribute and sell over-the-counter Zantac from about January 2017 to the present, and manufactured and distributed the drug in the United States during that period.

FACTUAL ALLEGATIONS

14. Ranitidine is a drug that decreases stomach acid production. Marketed under the trade name Zantac and also generically under store brands, ranitidine is commonly recommended to both adults and children for the treatment of ulcers, gastroesophageal reflux, and other medical conditions. Ranitidine is sold both in both over-the-counter and prescription dosages, in both tablet and syrup forms.

15. Based on its effectiveness, low cost and reputation for safety, ranitidine is listed on the World Health Organization's ("WHO") Model List of Essential Medicines, a list of the most efficacious, safe and cost–effective medicines.

16. On September 9, 2019, Valisure, an independent pharmacy, submitted a citizen petition to the U.S. Food and Drug Administration ("FDA") requesting suspension of ranitidine sales. Valisure reported that their internal testing of ranitidine samples "detected extremely high levels of N-Nitrososdimethylamine ("NDMA"), a probable human carcinogen according to the WHO, in every lot tested, across multiple manufacturers and dosage forms of the drug ranitidine."[1]

17. According to the WHO, NDMA is classified as a probable carcinogen, which means it probably causes cancer in humans.

18. According to Valisure, ranitidine reacts with itself due to a molecular instability, and produces NDMA levels in excess of 3,000,000 ng per 150mg tablet, which is more than

[1] Valisure Citizen Petition, Sept. 9, 2019, https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (hereinafter, "Valisure Petition").

31,000 times the FDA's maximum daily intake amount of 96 ng/day. Valisure tested several brands of ranitidine including Zantac and drugstore brands, and each sample had levels of NDMA in excess of 2.4 million ng per 150mg tablet.[2]

19. According to the Valisure Petition, testing designed to simulate what happens to ranitidine in the human body shows that ingestion of ranitidine results in exposure to unacceptably high levels of NDMA.

20. On September 13, 2019, the FDA issued a MedWatch Alert stating that NDMA was reportedly found in ranitidine medicines, including Zantac.[3] Although the FDA did not call for people to stop taking ranitidine, it did suggest that patients and consumers taking ranitidine could consider using other medicines approved for their condition.

21. On September 24, 2019, the FDA issued an alert concerning "a voluntary recall of 14 lots of prescription ranitidine capsules distributed by Sandoz Inc." due to the presence of NDMA.[4] The alert cautioned that, "While the FDA investigates the root cause and risk, consumers and patients can continue to take ranitidine that has not been recalled." The FDA also stated that it was testing ranitidine and asked drug makers "to begin their own laboratory testing to examine levels of NDMA in ranitidine and to send samples of ranitidine to the FDA to be tested by agency scientists."

22. On September 26, 2019, the FDA issued an update, alerting the public to a voluntary recall of over-the-counter ranitidine tablets (75 mg and 150 mg), labeled by

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[2] Valisure Petition https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf at 6.
[3] FDA MedWatch, *Zantac (ranitidine): Safety Information - NDMA Found in Samples of Some Ranitidine Medicines*, https://www.fda.gov/safety/medwatch-safety-alerts-human-medical-products/zantac-ranitidine-safety-information-ndma-found-samples-some-ranitidine-medicines
[4] *FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity,* https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity

Walgreens, Walmart, and Rite-Aid and manufactured by Apotex Corp." due to the presence of NDMA in the tablets.[5]

23. On October 2, 2019, the FDA issued another update, stating that "the agency's early, limited testing found unacceptable levels of NDMA in samples of ranitidine."[6]

24. Since these initial reports, public health and safety regulators in several other countries began withdrawing ranitidine drugs from the market. Canada requested that sellers stop distributing ranitidine in Canada pending further testing. Regulators in Austria, Finland, Germany, Pakistan, Singapore, Switzerland, the U.A.E., all took action to warn consumers and suspend ranitidine sales in their respective health systems.

25. Notwithstanding the growing evidence from numerous sources that ranitidine contains high levels of NDMA, the FDA has not ordered a recall of ranitidine drugs in the United States or recommended that consumers switch to a different drug.

26. Finally, on October 18, 2019 Sanofi announced a voluntary recall of over-the-counter Zantac.

27. Sanofi either knew or had reason to know that ranitidine drugs, including Zantac, expose users to unsafe levels of NDMA when used as directed. The Valisure Petition cites to numerous examples of scientific literature suggesting both that ranitidine reacts to form NDMA in the human body and that NDMA exposure is carcinogenic in humans.

28. Sanofi never disclosed that consumers who use Zantac as directed are exposed to unsafe levels of NDMA.

[5] FDA Updates and Press Announcements on NDMA in Zantac (ranitidine) https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine

[6] FDA Updates and Press Announcements on NDMA in Zantac (ranitidine) https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine

29. A reasonable consumer would not have purchased Zantac or other ranitidine had they known that ranitidine exposes the user to unsafe levels of NDMA, a probable carcinogen. This is particularly true given the availability of other stomach-acid-reducing drugs that do not contain ranitidine and are known to not form NDMA.

30. Defendants failure to disclose that Zantac exposed consumers to unsafe levels of NDMA when used as directed was deceptive and misleading.

CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action individually and as representative of all those similarly situated pursuant to Federal Rule of Civil Procedure 23 on behalf of the below-defined Class of all persons in the state of New York that purchased Zantac over-the-counter ("OTC") since January 1, 2017. Excluded from the Class are Defendants and their affiliates, parents, subsidiaries, employees, officers, agents, and directors. Also excluded are any judicial officers presiding over this matter and the members of their immediate families and judicial staff and purchasers for resale.

32. The members of the Class are so numerous that their individual joinder herein is impracticable. Zantac had sales of $127 million in 2018 alone, and New York is the fourth most populous state in the United States. On information and belief, Class members number in the tens or hundreds of thousands. The precise number of Class members and their addresses are presently unknown to Plaintiff, but may be ascertained from pharmacy and other records. Class members may be notified of the pendency of this action by mail, email, Internet postings, and/or publication.

33. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Such common questions of law or fact include:

a. Whether Zantac exposes people to unsafe levels of NDMA;

b. Whether and when Defendants knew or should have known that Zantac exposes people to unsafe levels of NDMA;

c. Whether Defendants failed to disclose that the use of Zantac results in exposure to unsafe levels of NDMA;

d. Whether the undisclosed information about NDMA in Zantac was material;

e. Whether Defendants' failures to disclose rendered Defendants' marketing of Zantac deceptive;

f. Whether Defendants' acts and omission violate GBL § 349.

34. Plaintiff's claims are typical of the claims of the other members of the Class because, among other things, all Class members were suffered the same type of injury, namely, paying for a product that they otherwise would not have purchased had Defendants disclosed the presence of NDMA in Zantac. Further, there are no defenses available to Defendants that are unique to Plaintiff.

35. Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the other Class members she seeks to represent, she has retained counsel competent and experienced in class action litigation, and she and her counsel will prosecute this action vigorously. The Class members' interests will be fairly and adequately protected by Plaintiff and her counsel.

36. A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other members of the Class individually are relatively small compared to the burden and expense that would be required to separately litigate their claims against Defendants, so it would be uneconomical and impracticable for Class members to individually seek redress for Defendants' wrongful conduct. Even if Class members could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

COUNT I

Violation of the Unfair and Deceptive Trade Practices Act New York GBL § 349, *et seq*.

37. Plaintiff incorporates paragraphs 1-36 as if fully set forth herein.

38. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

39. By the acts, omissions and other misconduct alleged herein, Defendants committed unfair or deceptive acts and practices.

40. The foregoing deceptive acts and practices were directed at consumers.

41. Defendants' foregoing deceptive acts and practices, including their omissions, are misleading in a material way because they fundamentally misrepresent the characteristics, ingredients, and benefits of Zantac to induce consumers to purchase same.

42. Defendants' foregoing deceptive acts and practices, including their omissions, were and are deceptive acts or practices in violation of New York's General Business Law section 349, Deceptive Acts and Practices, N.Y. Gen. Bus. Law 349, *et seq.*, in that:

a. Defendants manufactured, labeled, packaged, marketed, advertised, distributed and/or sold Zantac when they knew, or should have known, that using Zantac would expose the user to unsafe levels of NDMA, a probable carcinogen;

b. Defendants knew or should have known that information about the existence of NDMA in Zantac was unknown to, would not be easily discovered by, and would have been material to, Plaintiff and members of the Class, and would defeat their ordinary, foreseeable and reasonable expectations concerning the safety of Zantac; and

c. Plaintiff and the members of the Class were deceived by Defendants' failure to disclose, and could not discover on their own, the risk of exposure to unsafe levels of NDMA from Zantac, prior to purchasing Zantac.

43. Defendants' foregoing deceptive acts and practices, including their omissions, were likely to deceive, and did deceive, consumers acting reasonably under the circumstances.

44. Plaintiff and members of the Class were injured because (a) they would not have purchased Zantac if they had known that it exposes users to unsafe levels of NDMA; (b) they paid a price premium for Zantac based on the false perception of safety created by Defendants' omissions; and (c) Zantac does not have the characteristics, uses, or benefits as promised, namely a safe stomach acid reducer. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and members of the Class have been damaged either in the full amount of the purchase price of the product or in the difference in value between the Zantac with the risks of NDMA disclosed and the Zantac as actually sold.

45. On behalf of herself and other members of the Class, Plaintiff seeks to recover damages and costs of suit and reasonable attorneys' fees.

PRAYER FOR RELIEF

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

a. For an order certifying the Class under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as a representative of the Class and Plaintiffs' attorneys as Class Counsel to represent the Class members;

b. For an order finding in favor of Plaintiff and the Class on all counts asserted herein;

c. For damages in amounts to be determined by the Court and/or jury;

d. For prejudgment interest on all amounts awarded;

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

f. For an order awarding Plaintiff and the Class their reasonable attorneys' fees and expenses and costs of suit.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all claims so triable.

Dated: November 12, 2019

Respectfully submitted,

/s/ Zahra R. Dean

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