UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STACEY KOPPELL and DAN ZHOVTIS, on behalf of themselves and all others similarly situated, Plaintiffs, v. PERRIGO COMPANY PLC, PERRIGO RESEARCH & DEVELOPMENT COMPANY, CVS HEALTH CO., and WAL-MART STORES, INC., Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Stacey Koppell and Dan Zhovtis (collectively, "Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendants Perrigo Company PLC, Perrigo Research & Development Company (together with Perrigo Company PLC, "Perrigo"), CVS Health Co. ("CVS"), and Wal-Mart Stores, Inc. ("Walmart") (collectively, "Defendants"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

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

2. Ranitidine is an over-the-counter medication that is designed to decrease the amount of acid created by the stomach. Defendant CVS sells ranitidine medication

manufactured and distributed by Perrigo under the brand name CVS Health Acid Reducer ("CHAR"). Defendant Walmart sells ranitidine medication manufactured and distributed by Perrigo under the brand name Equate Ranitidine Tablets ("Equate").

3. CHAR and Equate are intended to be used for the treatment of heartburn associated with indigestion and sour stomach. However, Perrigo's manufacturing process has caused the CHAR and Equate medications to contain dangerously high levels of NDMA.

4. 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."

5. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine-containing medications.[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]

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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.

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

7. On October 8, 2019, Perrigo "halted shipments of [ranitidine] based upon preliminary test results." On October 23, 2019, Perrigo issued a voluntary recall of all of its ranitidine medications due to the "possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA)."[3] Perrigo explained that "[b]ased on the totality of data gathered to date, Perrigo has made the decision to conduct [a] voluntary recall."[4]

A. CHAR And Equate Are Marketed As Safe

8. Defendants CVS and Walmart marketed CHAR and Equate as safe and effective products.

9. On Defendant CVS's website, CVS writes, "Quality is our commitment."

10. On Defendant Walmart's website, Walmart writes, "Equate allows you to take care of your family with confidence."

11. NDMA is not listed as an ingredient in either the CHAR or Equate ranitidine products. That is because the presence of NDMA manifested from a manufacturing defect in the creation of the medications. It is not intended to be in either product, hence the recall.

12. Further, Perrigo advertises on its website that it makes "quality, affordable self-care products." On its gastrointestinal medications, Perrigo touts it "is committed to providing

[3] Food & Drug Admin., Perrigo Company PLC Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimenthylamine (NDMA) Impurity in the Product (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n.
[4] *Id.*

high-quality … gastrointestinal products that consumers can count on …. When it comes to GI relief, you can trust Perrigo products to alleviate your symptoms."

13. In short, when consumers go to a CVS or Walmart store and purchase CHAR or Equate respectively, they expect that the medications will be safe and effective for the purpose for which it is purchased. They do not expect, and Defendants do not disclose, that the medications contain the harmful impurity NDMA.

B. CHAR And Equate Contain Dangerous Levels Of NDMA

14. Contrary to the above assertions, CHAR and Equate contain dangerously high levels of NDMA that would not be present if the medications were properly synthesized. As noted in paragraph 5, *supra*, the FDA has found unacceptable levels of NDMA in samples of ranitidine. Perrigo's internal testing has also revealed unacceptable levels of NDMA, necessitating a recall of its ranitidine-containing medications.

15. The Medicines and Healthcare Products Regulatory Agency of the United Kingdom has issued an alert regarding ranitidine medications, 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."[5] "The MHPRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue."[6]

16. In the case of CHAR, Equate, other ranitidine medications, the cause of the NDMA contamination is still being investigated by the FDA and other regulatory agencies.

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[5] 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.

[6] *Id*.

However, the Health Products Regulatory Authority of Ireland, in issuing a recall of ranitidine medications, has stated: "The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India."[7]

17. The FDA has established a "permissible daily intake limit for…NDMA of 96 [nanograms]."[8] But Equate and CHAR, according to testing by Valisure, an FDA-registered online pharmacy,[9] have an NDMA content of between 2.4-2.8 million nanograms *per tablet*:

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

C. Plaintiffs Were Harmed By Purchasing And Consuming Defective CHAR And Equate Medications Manufactured And Sold By Defendants

18. Plaintiffs and the Class and Subclasses were injured by the full purchase price of their CHAR and Equate medications. These medications are worthless, as they contain harmful levels of NDMA, which is underscored by Perrigo's "voluntary, worldwide product recall to the

[7] Health Products Regulatory Authority, Precautionary Pharmacy and Retail Level Recall of Several Batches of a Number of Ranitidine Medicines in Ireland (Sept. 23, 2019), https://www.hpra.ie/homepage/medicines/safety-notices/item?t=/precautionary-pharmacy-and-retail-level-recall-of-several-batches-of-a-number-of-ranitidine-medicines-in-ireland&id=d26b0c26-9782-6eee-9b55-ff00008c97d0.
[8] 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").
[9] *Id*. at 6.

retail customer level of ranitidine."[10] As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiffs are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendants' conduct.

19. Plaintiffs bring this action on behalf of themselves and the Classes 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 New York's General Business Law § 349, (iv) violation of New York's General Business Law § 350, (v) violation of the Virginia Consumer Protection Act, Va. Code Ann. §§ 59.1-196, *et seq.*, (vi) unjust enrichment, (vii) fraudulent concealment, (viii) fraud, and (ix) conversion.

PARTIES

20. Plaintiff Stacey Koppell is a citizen of New York who resides in New York, New York. During all relevant time periods, Ms. Koppell purchased and consumed CHAR medication manufactured by Perrigo and sold by Defendant CVS. Ms. Koppell originally learned about the ranitidine defect through news sources reporting NDMA in ranitidine medications. When purchasing her CHAR medication from Perrigo and CVS, Ms. Koppell reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the CHAR medication she purchased were properly manufactured and free from carcinogenic contaminants such as NDMA. Ms. Koppell relied on these representations and warranties in deciding to purchase her CHAR

[10] Food & Drug Admin., Perrigo Company PLC Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimenthylamine (NDMA) Impurity in the Product (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n.

medication from Perrigo and CVS, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her CHAR medication from Perrigo and CVS if she had known that it was not, in fact, properly manufactured, and contained the carcinogenic impurity NDMA. Ms. Koppell also understood that in making the sale, CVS was acting with the knowledge and approval of Perrigo and/or as the agent of Perrigo. Ms. Koppell also understood that each purchase involved a direct transaction between herself and Perrigo because her medication came with packaging and other materials prepared by Perrigo, including representations and warranties that her medication was properly manufactured, free from carcinogenic impurities such as NDMA, and safe for use.

21. Plaintiff Dan Zhovtis is a citizen of Virginia who resides in Fredericksburg, Virginia. During all relevant time periods, Mr. Zhovtis purchased and consumed Equate medication manufactured by Perrigo and sold by Defendant Walmart. Mr. Zhovtis originally learned about the ranitidine defect through news sources reporting NDMA in ranitidine medications. When purchasing his Equate from Perrigo and Walmart, Mr. Zhovtis reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Equate medication was properly manufactured and free from carcinogenic contaminants such as NDMA. Mr. Zhovtis relied on these representations and warranties in deciding to purchase his Equate medication from Perrigo and Walmart, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his Equate medication from Perrigo and Walmart if he had known that it was not, in fact, properly manufactured, and contained the carcinogenic impurity NDMA. Mr. Zhovtis also understood that in making the sale, Walmart was acting with the knowledge and approval of Perrigo and/or as the agent of Perrigo. Mr. Zhovtis also understood

that each purchase involved a direct transaction between himself and Perrigo because his medication came with packaging and other materials prepared by Perrigo, including representations and warranties that his medication was properly manufactured, free from carcinogenic impurities such as NDMA, and safe for use.

22. Defendant Perrigo Company PLC is a corporation registered in Ireland, and maintains a headquarters in Dublin, Ireland. The Perrigo Company PLC is registered in Ireland for tax purposes. [11] Perrigo Company PLC maintains a primary operating headquarters in the United States at 515 Eastern Avenue, Allegan, Michigan 49010. [12] Perrigo Company PLC conducts substantial business in the United States, and the vast majority of its sales are in the United States. Perrigo Company PLC does substantial business in the State of New York. Perrigo Company PLC has been engaged in the manufacturing, distribution, and sale of defective ranitidine throughout the United States, including in the States of New York and Virginia.

23. Defendant Perrigo Research & Development Company is a corporation organized under the laws of Michigan with a principal place of business at 601 Abbot Road, East Lansing, Michigan 48823. Perrigo Research & Development Company is the holder of Abbreviated New Drug Application ("ANDA") 091429, [13] which is the ranitidine used in CHAR and Equate.

24. Upon information and belief, Defendant Perrigo Research & Development Company is a wholly owned subsidiary of Perrigo Company PLC. There exists, and at all times

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[11] *Tracking Tax Runaways*, BLOOMBERG (Mar. 1, 2017), https://www.bloomberg.com/graphics/tax-inversion-tracker/ (last visited 10/25/19).
[12] Perrigo Company PLC, LINKEDIN, https://www.linkedin.com/company/perrigo (explaining that Perrigo Company PLC "sells its products primarily in North America and Europe") (last visited 10/30/19).
[13] Food & Drug Admin., Product Details for ANDA 091429, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=091429#37634 (last visited Oct. 30, 2019).

herein existed, a unity of ownership between Perrigo Company PLC, Perrigo Research & Development Company, and their agents such that any individuality or separateness between them has ceased and each of them is the alter ego of the other. Upon information and belief, Perrigo Company PLC communicates with Perrigo Research & Development Company concerning virtually all aspects of the ranitidine-containing medications it distributes in the United States. At all relevant times, Perrigo Research & Development Company acted as an authorized agent, representative, servant, employee and/or alter ego of Perrigo Company PLC while performing activities including but not limited to advertising, warranties, dissemination of information, and distribution of ranitidine-containing medications in the United States and in the State of New York.

25. Defendant CVS Health Co. is a corporation organized under the laws of the State of Rhode Island and Providence Plantations and maintains its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS sells ranitidine medication manufactured and distributed by Perrigo under the brand name CHAR. Defendant CVS conducts substantial business throughout the United States, and specifically in the State of New York. Ms. Koppell purchased CHAR from a CVS store in New York, New York.

26. Defendant Wal-Mart Stores, Inc. is a corporation organized under the laws of Delaware and maintains its principal place of business at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart sells ranitidine medication manufactured and distributed by Perrigo under the brand name Equate. Defendant Walmart conducts substantial business throughout the United States, and specifically in New York and Virginia. Mr. Zhovtis purchased his Equate medication from a Walmart store in Fredericksburg, Virginia.

JURISDICTION AND VENUE

27. 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 Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

28. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff Koppell resides in this District, many of the acts and transactions giving rise to this action occurred in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of defective CHAR and Equate medications in this District, including the sale of defective CHAR medications to Plaintiff Koppell; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

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

30. Plaintiff Koppell seeks to represent a subclass of all Class members who purchased ranitidine-containing medications manufactured by Perrigo in New York (the "New York Subclass").

31. Plaintiff Zhovtis seeks to represent a subclass of all Class members who purchased ranitidine-containing medications manufactured by Perrigo in Virginia (the "Virginia Subclass") (collectively, the "Subclasses").

32. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Class and Subclasses may be expanded or narrowed by amendment or amended complaint.

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

34. **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 Subclasses and predominate over any questions affecting only individual members of the Class and Subclasses. These common legal and factual questions include, but are not limited to, the following:

(a) whether the ranitidine medications, including the CHAR and Equate medications,

manufactured, distributed, and sold by Defendants contain dangerously high levels of NDMA, thereby breaching the express and implied warranties made by Defendants and making the ranitidine-containing medications unfit for human consumption and therefore unfit for their intended purpose;

(b) whether Defendants knew or should have known that the ranitidine-containing medications, including the CHAR and Equate medications, contained elevated levels of NDMA prior to selling the medications, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendants have unlawfully converted money from Plaintiffs and the Class and Subclasses;

(d) whether Defendants are liable to Plaintiffs and the Class and Subclasses for unjust enrichment;

(e) whether Defendants are liable to Plaintiffs and the Class and Subclasses for fraudulent concealment;

(f) whether Defendants are liable to Plaintiff Koppell and the New York Subclass for violations of the New York consumer-protection laws;

(g) whether Defendants are liable to Plaintiff Zhovtis and the Virginia Subclass for violations of the Virginia consumer-protection laws;

(h) whether Defendants are liable to Plaintiffs and the Class and Subclasses for breaches of express and implied warranties;

(i) whether Plaintiffs and the Class and Subclasses have sustained monetary loss and the proper measure of that loss;

(j) whether Plaintiffs and the Class and Subclasses are entitled to declaratory and injunctive relief;

(k) whether Plaintiffs and the Class and Subclasses are entitled to restitution and disgorgement from Defendants; and

(l) whether the marketing, advertising, packaging, labeling, and other promotional materials for the ranitidine-containing medications, including the CHAR and Equate medications, are deceptive.

35. **Typicality.** Plaintiffs' claims are typical of the claims of the other members of the Class and Subclasses in that Defendants mass marketed and sold defective ranitidine-based medications, including the CHAR and Equate medications, to consumers throughout the United States. This defect was present in all of the ranitidine-containing medications, including the CHAR and Equate medications, manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiffs and members of the Class and Subclasses by manufacturing, distributing, and selling the defective ranitidine-containing medications, including the CHAR and Equate medications. Plaintiffs' claims are typical in that they and members of the Class and Subclasses were uniformly harmed in purchasing and consuming the defective ranitidine-containing medications, including the CHAR and Equate medications. Plaintiffs' claims are further typical in that Defendants deceived Plaintiffs in the very same manner as they deceived each member of the Class and Subclasses. Further, there are no defenses available to Defendants that are unique to Plaintiffs.

36. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class and Subclasses. Plaintiffs have retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class and Subclasses. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class and Subclasses.

37. **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 members of the Class and Subclasses are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class and Subclasses, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Class and Subclasses 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.

38. In the alternative, the Class and Subclasses may also be certified because:

(a) the prosecution of separate actions by individual members of the Class and Subclasses would create a risk of inconsistent or varying adjudications with respect to individual members of the Class and Subclasses that would establish incompatible standards of conduct for the Defendants;

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

(c) Defendants have acted or refused to act on grounds generally applicable to

members of the Class and Subclasses as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and Subclasses as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Class And Subclasses)

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

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

41. Plaintiffs, and each member of the Class and Subclasses, formed a contract with Defendants at the time Plaintiffs and the other members of the Class and Subclasses purchased the defective CHAR and Equate medications. The terms of the contract include the promises and affirmations of fact made by Defendants on the CHAR and Equate medication's packaging and through marketing and advertising, including that the products 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 Plaintiffs and the members of the Class and Subclasses and Defendants.

42. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that CHAR and Equate medications would contain only the ingredients stated on the label, and not harmful impurities such as NDMA.

43. Plaintiffs relied on the express warranty that their CHAR and Equate medications contained only what was stated on the label, and did not contain NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiffs

and the members of the Class and Subclasses and Defendants.

44. Defendants breached that express warranty because the medications contained NDMA, a carcinogenic impurity.

45. Plaintiffs and the Class and Subclasses performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medications.

46. Defendants breached express warranties about the defective CHAR and Equate medications and their qualities because Defendants' statements about the defective CHAR and Equate medications were false and the defective CHAR and Equate medications do not conform to Defendants' affirmations and promises described above.

47. Plaintiffs and each of the members of the Class and Subclasses would not have purchased the defective CHAR and Equate medications had they known the true nature of the medications, specifically that CHAR and Equate medications contained elevated levels of NDMA.

48. As a result of Defendants' breaches of express warranty, Plaintiffs and each of the members of the Class and Subclasses have been damaged in the amount of the purchase price of the CHAR and Equate medications and any consequential damages resulting from the purchases.

49. On October 30, 2019, prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiffs' counsel sent Defendants 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 Plaintiffs' counsel's letter is attached hereto as **Exhibit A**.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And Subclasses)

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

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

52. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the CHAR and Equate medications (i) would not contain elevated levels of NDMA and (ii) are generally recognized as safe for human consumption.

53. Defendants breached the warranty implied in the contract for the sale of the defective CHAR and Equate medications because they could not pass without objection in the trade under the contract description, the CHAR and Equate medications were not of fair or average quality within the description, and the CHAR and Equate medications were unfit for their intended and ordinary purpose because the CHAR and Equate medications manufactured, distributed, and sold by Defendants were defective in that they contained elevated levels of carcinogenic and liver-toxic NDMA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiffs and members of the Class and Subclasses did not receive the goods as impliedly warranted by Defendants to be merchantable.

54. Plaintiffs and members of the Class and Subclasses purchased the CHAR and Equate medications in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

55. The CHAR and Equate medications were not altered by Plaintiffs or members of the Class and Subclasses.

56. The CHAR and Equate medications were defective when it left the exclusive control of Defendants.

57. Defendants knew that the CHAR and Equate medications would be purchased and used without additional testing by Plaintiffs and members of the Class and Subclasses.

58. The CHAR and Equate medications were defectively manufactured and unfit for their intended purpose, and Plaintiffs and members of the Class and Subclasses did not receive the goods as warranted.

59. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiffs and members of the Class and Subclasses have been injured and harmed because: (a) they would not have purchased the CHAR and Equate medications on the same terms if they knew that the CHAR and Equate medications contained harmful levels of NDMA, and are not generally recognized as safe for human consumption; and (b) the CHAR and Equate medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

60. As a result of Defendants' breach of implied warranty, Plaintiffs and each of the members of the Class and Subclasses have been damaged in the amount of the purchase price of the CHAR and Equate medications and any consequential damages resulting from the purchases.

COUNT III
Violation Of New York General Business Law § 349
(On Behalf Of The New York Subclass)

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

62. Plaintiff Koppell brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

63. New York's General Business Law § 349 prohibits deceptive acts or practices in

the conduct of any business, trade, or commerce.

64. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

65. Plaintiff Koppell and members of the New York Subclass are consumers who purchased products from Defendants for their personal use.

66. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the CHAR and Equate medications: (i) would not contain dangerously high levels of NDMA; and (ii) are generally recognized as safe for human consumption.

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

68. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of CHAR and Equate medications to induce consumers to purchase the same.

69. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

70. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff Koppell and members of the New York Subclass have sustained from having paid for and used Defendants' products.

71. As a result of Defendants' violations, Plaintiff Koppell and members of the New York Subclass have suffered damages because: (a) they would not have purchased CHAR and Equate on the same terms if they knew that CHAR and Equate contained high levels of NDMA; and (b) the CHAR and Equate medications do not have the characteristics, uses, benefits, or

qualities as promised.

72. On behalf of herself and other members of the New York Subclass, Plaintiff Koppell seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York General Business Law § 350
(On Behalf Of The New York Subclass)

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

74. Plaintiff Koppell brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

75. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

76. New York's General Business Law § 350 defines false advertising as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

77. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of New York's General Business Law, as set forth at length above.

78. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

79. Defendants' false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

80. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

81. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff Koppell and the New York Subclass have suffered and continue to suffer economic injury.

82. As a result of Defendants' violations, Plaintiff Koppell and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased the CHAR and Equate medications on the same terms if they knew that the CHAR and Equate medications contained elevated levels of NDMA and are not safe for human consumption; and (b) the CHAR and Equate medications do not have the characteristics, uses, benefits, or qualities as promised.

83. On behalf of herself and the other members of the New York Subclass, Plaintiff Koppell seeks to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Violation Of the Virginia Consumer Protection Act, Va. Code Ann. § 59.1-196, et seq.
(On Behalf Of The Virginia Subclass)

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

85. Plaintiff Zhovtis brings this claim individually and on behalf of the members of the proposed Virginia Subclass against Defendants.

86. Plaintiff Zhovtis and the Virginia Subclass members are consumers who purchased CHAR and Equate medications from Defendants for their personal use, as defined by Va. Code. Ann. § 59.1-198.

87. Defendants are "Persons" and "Suppliers" as defined by Va. Code Ann. § 59.1-198.

88. Under Va. Code Ann. § 59.1-200(A)(6), Defendants had a duty not to mispresent that their CHAR and Equate medications were of a particular standard, quality, style, or model.

89. By the acts and conduct alleged herein, Defendants violated this duty when they mispresented the standards and qualities of their CHAR and Equate medications, including by misrepresenting, without limitation, that their CHAR and Equate medications (i) would not contain dangerously high levels of NDMA; and (ii) are generally recognized as safe for human consumption.

90. The foregoing misrepresentations were directed at consumers.

91. The foregoing misrepresentations were misleading in a material way because they fundamentally misrepresented the standards and quality of the CHAR and Equate medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

92. As a result of Defendants' violation of the Virginia Consumer Protection Act, Plaintiff Zhovtis and members of the Virginia Subclass suffered and continue to suffer economic injury.

93. As a result of Defendants' violations, Plaintiff Zhovtis and members of the Virginia Subclass have suffered damages due to said violations because: (a) they would not have purchased the CHAR and Equate medications on the same terms if they knew that the CHAR and Equate medications contained elevated levels of NDMA and are not safe for human consumption; and (b) the CHAR and Equate medications do not have the characteristics, uses, benefits, or qualities as promised. *See* Va. Code Ann. § 59.1-200(A)(5)

94. By reason of this conduct, Defendants engaged in deceptive conduct in violation

of Virginia Consumer Protection Act.

95. Plaintiff Zhovtis and members of the Virginia Subclass relied on Defendants' representations, to their detriment

96. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff Zhovtis and members of the Virginia Subclass have sustained from having paid for and consumed Defendants' products.

97. As a result of Defendants' violations, Plaintiff Zhovtis and members of the Virginia Subclass have been injured because: (a) they would not have purchased Defendants' ranitidine-containing medications, including the CHAR and Equate medications, on the same terms if they knew that CHAR and Equate contained high levels of NDMA; and (b) the CHAR and Equate medications do not have the characteristics, uses, benefits, or qualities as promised.

98. On behalf of himself and other members of the Virginia Subclass, Plaintiff Zhovtis seeks to recover his actual damages or $500, whichever is greater, treble damages or $1,000, whichever is greater, attorneys' fees and costs, injunctive relief enjoining Defendants continuing their misleading practices, and any other relief the Court deems just and proper.

COUNT VI
Unjust Enrichment
(On Behalf Of The Class And Subclasses)

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

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

101. Plaintiffs and the Class and Subclasses conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective CHAR and Equate medications.

102. Defendants voluntarily accepted and retained this benefit.

103. 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 Defendants to retain it without paying the value thereof.

COUNT VII
Fraudulent Concealment
(On Behalf Of The Class and Subclasses)

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

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

106. Defendants had a duty to disclose material facts to Plaintiffs and the Class and Subclasses given their relationship as contracting parties and intended users of the ranitidine-containing medications, including the CHAR and Equate medications. Defendants also had a duty to disclose material facts to Plaintiffs and the Class and Subclasses, namely that they were in fact manufacturing, distributing, and selling harmful ranitidine-containing medications, including the CHAR and Equate medications, containing NDMA that were unfit for human consumption. Such duty to disclose exists because Defendants had superior knowledge that the medications were defective and contained harmful levels of NDMA such that the transactions without the disclosure were rendered inherently unfair.

107. Defendants 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."[14] Furthermore, a 2016 study by Stanford University found that individuals who took

[14] VALISURE PETITION at 4-5.

ranitidine medications had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[15] During that time, Plaintiffs and members of the Class and Subclasses were using the CHAR and Equate medications without knowing it contained dangerous levels of NDMA.

108. Defendants failed to discharge their duty to disclose these materials facts.

109. In so failing to disclose these material facts to Plaintiffs and the Class and Subclasses, Defendants intended to hide from Plaintiffs and the Class and Subclasses that they were purchasing and consuming CHAR and Equate medications with harmful defects that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

110. Plaintiffs and the Class and Subclasses reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective CHAR and Equate medications manufactured, distributed, and sold by Defendants had they known the medications contained unsafe levels of NDMA.

111. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiffs and the Class and Subclasses suffered damages in the amount of monies paid for the defective CHAR and Equate medications.

112. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Fraud
(On Behalf Of The Class and Subclasses)

113. Plaintiffs hereby incorporate by reference the allegations contained in all

[15] 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/.

preceding paragraphs of this complaint.

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

115. As discussed above, Defendants provided Plaintiffs and members of the Class and Subclasses with materially false or misleading information about their ranitidine-containing medications, including the CHAR and Equate medications, manufactured, distributed, and sold by Defendants. Specifically, Defendants have marketed the ranitidine-containing medications, including the CHAR and Equate medications, as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' ranitidine-containing medications, including the CHAR and Equate medications, contained elevated levels of NDMA.

116. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiffs and members of the Class and Subclasses reasonably and justifiably relied, were intended to induce and actually induced Plaintiffs and members of the Class and Subclasses to purchase the defective ranitidine-containing medications, including the CHAR and Equate medications.

117. Defendants knew that the ranitidine-containing medications, including the CHAR and Equate medications, were 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."[16] Furthermore, a 2016 study by Stanford University found that individuals who took ranitidine medications had "NDMA levels [in their

[16] VALISURE PETITION at 4-5.

urine] more than 400 times greater than what the FDA considers acceptable."[17] During that time, Plaintiffs and members of the Class and Subclasses were using the medications without knowing that they contained dangerous levels of NDMA.

118. The fraudulent actions of Defendants caused damage to Plaintiffs and members of the Class and Subclasses, who are entitled to damages and other legal and equitable relief as a result.

119. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT IX
Conversion
(On Behalf Of The Class And Subclasses)

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

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

122. Plaintiffs and the Class and Subclasses have an ownership right to the monies paid for the defective ranitidine-containing medications, including the CHAR and Equate medications, manufactured, distributed, and sold by Defendants.

123. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective ranitidine-containing medications, including the CHAR and Equate medications. Defendants have done so every time that Plaintiffs and the Class and Subclasses bought the ranitidine-containing medications, including the CHAR and Equate medications.

[17] 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/.

124. As a direct and proximate cause of Defendants' conversion, Plaintiffs and the Class and Subclasses suffered damages in the amount of the payments made for each time they bought the CHAR and Equate medications over the counter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendants, as follows:

A. For an order certifying the Class and the Subclasses under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as the representatives of the Class and Subclasses and Plaintiffs' attorneys as Class Counsel;

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

C. For an order finding in favor of Plaintiffs, the Class, and the Subclasses 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;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiffs and the Class and Subclasses their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

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

Dated: November 4, 2019

Respectfully submitted,

BURSOR & FISHER, P.A.

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

Joseph I. Marchese
Andrew J. Obergfell
888 Seventh Avenue
New York, NY 10019
Telephone: (212) 837-7150
Facsimile: (212) 989-9163
Email: jmarchese@bursor.com
aobergfell@bursor.com

BURSOR & FISHER, P.A.
Neal J. Deckant
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
Email: ndeckant@bursor.com

Attorneys for Plaintiffs

EXHIBIT A

BURSOR & FISHER
P.A.

888 SEVENTH AVENUE
3RD FLOOR
NEW YORK, NY 10019
www.bursor.com

ANDREW J. OBERGFELL
Tel: 646.837.7129
Fax: 212.989.9163
aobergfell@bursor.com

October 30, 2019

Via Certified Mail – Return Receipt Requested

Perrigo Company PLC
515 Eastern Avenue
Allegan, Michigan 49010

Perrigo Research & Development Company
601 Abbot Road
East Lansing, Michigan 48823

CVS Health Co.
One CVS Drive
Woonsocket, Rhode Island 02895

Wal-Mart Stores, Inc.
702 SW 8th Street
Bentonville, Arkansas 72716

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607;
New York's General Business Law §§ 349-350;
Virginia Consumer Protection Act § 59.1-196 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 Perrigo Company PLC, Perrigo Research & Development Company (collectively, "Perrigo"), CVS Health Co. ("CVS"), and Wal-Mart Stores, Inc. ("Walmart") 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 clients, Stacey Koppell and Dan Zhovtis, and a class of all similarly situated purchasers (the "Class") of defective ranitidine medications manufactured and distributed by Perrigo, and sold by CVS and Walmart under the brand names CVS Health Acid Reducer ("CHAR") and Equate Ranitidine Tablets ("Equate") respectively.

Our clients purchased CHAR and Equate medications containing ranitidine, manufactured and distributed by Perrigo, and sold by CVS and Walmart. Our clients' respective ranitidine medications were defective in that they 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 medications. The FDA has since found unacceptable levels of NDMA in samples of ranitidine, and Perrigo has issued a voluntary recall of all of its ranitidine medications due to the "possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA)." In short, the ranitidine medications that our clients and the Class were purchasing are worthless, as they contain NDMA, rendering them unusable and unfit for human consumption. Perrigo, CVS, and Walmart each violated express and implied warranties made to our clients and the Class regarding the quality and safety of the ranitidine medications they purchased. *See* U.C.C. §§ 2-313, 2-314.

Additionally, this letter also serves as notice of violation of New York's General Business Law §§ 349 and 350, the Virginia Consumer Protection Act, and all other relevant state and local laws. As a result of Perrigo, CVS, and Walmart's violation of New York General Business Law § 349 and § 350 and the Virginia Consumer Protection Act, Ms. Koppell and Mr. Zhovtis sustained injury.

On behalf of our clients and the Class, we hereby demand that Perrigo, CVS, and Walmart immediately (1) cease and desist from continuing to sell defective ranitidine medications and (2) make full restitution to all purchasers of the defective ranitidine medications of all purchase money obtained from sales thereof.

We also demand that Perrigo, CVS, and Walmart 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 Perrigo's ranitidine medications;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of ranitidine medications manufactured and distributed by Perrigo;

3. All tests of ranitidine medications manufactured and distributed by Perrigo;

4. All documents concerning the pricing, advertising, marketing, and/or sale of ranitidine medications manufactured and distributed by Perrigo;

5. All communications with customers involving complaints or comments concerning the ranitidine medications manufactured and distributed by Perrigo;

6. All documents concerning communications with any retailer involved in the marketing or sale of ranitidine medications manufactured and distributed by Perrigo;

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

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

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