

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

JOSEPH CACACCIO, on behalf of himself
and all others similarly situated,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,
MYLAN N.V., RITE AID CORPORATION,

Defendants.

Civil Action No.

**CLASS ACTION COMPLAINT
AND DEMAND FOR JURY
TRIAL**

Plaintiff Joseph Cacaccio brings this action on behalf of himself and all others similarly situated against Defendants Mylan Pharmaceuticals, Inc. (“Mylan”), Mylan N.V. (collectively “the Mylan Defendants”), and Rite Aid Corporation (“Rite Aid”) (collectively “Defendants”). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding the Mylan Defendants’ and Rite Aid’s manufacturing, distribution, and sale of valsartan-containing generic prescription medications contaminated with N-nitrosodiethylamine (NDEA), a carcinogenic and liver-damaging impurity.

2. Originally marketed under the brand name Diovan, valsartan is a prescription medication mainly used for the treatment of high blood pressure and congestive heart failure. However, due to manufacturing defects originating from the Mylan Defendants’ overseas

laboratories in India, the Mylan Defendants have voluntarily recalled all non-expired lots of their valsartan-containing medications because they have been found to contain NDEA.

3. NDEA is classified as a probable human carcinogen. Animal studies have revealed the carcinogenic nature of the compound.

4. On July 13, 2018, the U.S. Food & Drug Administration (“FDA”) announced a voluntary recall of several brands of valsartan-containing generic medications. The recall traced back to a Chinese company, Zhejiang Huahai Pharmaceuticals, which supplied the active pharmaceutical ingredient, valsartan, to American subsidiaries, as well as other companies. The recall was due to the presence of N-nitrosodimethylamine (NDMA) in the recalled valsartan products. 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. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.”

5. Originally, the recall was thought to have been limited to manufacturing practices in China; however, over the next several months, recalls continued to expand to other overseas laboratories in India.

6. The widespread recalls caused the FDA to evaluate and test the valsartan-containing medications, which led to the FDA finding an additional impurity, NDEA, in several of the recalled medications. On November 20, 2018, the Mylan Defendants announced a voluntary nationwide recall of fifteen (15) lots of several of its valsartan-containing medications. Plaintiff Cacaccio was prescribed, purchased, and used valsartan medication from one of the contaminated lots. The fifteen lots of contaminated valsartan-containing medications manufactured and distributed by the Mylan Defendants are as follows:

NDC	Product Description	Strength	Size	Lot Number	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP	5mg/160mg	Bottles of 30	3066051	3/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP	10mg/160mg	Bottles of 30	3079500	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3061986	11/2018
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079709	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3077618	11/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079708	1/2020
0378-5813-77	Valsartan Tablets, USP	80mg	Bottles of 90	3063782	1/2019
0378-5814-77	Valsartan Tablets, USP	160mg	Bottles of 90	3071352	7/2019
0378-5807-93	Valsartan Tablets, USP	40mg	Bottles of 30	3061169	11/2018

0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3081499	3/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080009	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080010	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3079205	1/2020
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3084886	2/2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3093804	12/2019

7. The FDA announced that the recall was “due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC).”

8. After issuing a limited recall on November 20, 2018, the Mylan Defendants expanded their voluntary “nationwide recall to include all lots of Valsartan-containing products

within expiry.”¹ This represents a total of 104 additional lots recalled.

The Mylan Defendants failed to promptly recall their valsartan medications, even though Mylan sourced valsartan from overseas labs in India that were implicated in prior recalls.

9. After several waves of recalls by other companies, on November 20, 2018, the Mylan Defendants issued a voluntary recall of fifteen (15) lots of their valsartan-containing medications. Later, on December 4, 2018, the Mylan Defendants expanded the recall to all non-expired lots of their valsartan-containing medication due to the presence of NDEA.

10. Previous recalls, such as the Camber Pharmaceuticals recall announced on August 8, 2018, implicated specific manufacturing facilities in India as a source of contaminated valsartan medication. Despite this warning, the Myland Defendants failed to take immediate action.

11. Mylan N.V., acting in concert with Defendant Mylan Pharmaceuticals, Inc., its United States based affiliate, failed to promptly recall its valsartan-containing medications for over four months after the initial recall was announced, and over three months after labs in India were implicated. The Mylan Defendants failed to do so despite knowing that their valsartan-containing medication were also likely contaminated. It took the Mylan Defendants another two weeks to recall all non-expired lots of the medication due to the presence of NDEA.

12. The Mylan Defendants reaped a substantial windfall from this non-disclosure, as patients like Plaintiff Cacaccio and other class members were actually switched to Mylan’s valsartan-containing medications from previously-recalled brands.

13. Not only did Mylan benefit from patients being switched to their medications, but during the same period the price per tablet more than doubled, further contributing to Mylan’s

¹ <http://investor.mylan.com/news-releases/news-release-details/mylan-expands-its-voluntary-nationwide-recall-valsartan-tablets> (last visited 12/4/18).

windfall.² According to Reuters, “[t]he price of a 160 mg valsartan tablet rose to around 31 cents from 14 cents a month earlier.” All the while, the Mylan Defendants were manufacturing and distributing valsartan-containing medication contaminated with NDEA.

14. Like NDMA, NDEA is acutely toxic when consumed orally.

The Mylan Defendants boast the quality and safety of their valsartan products, even though they are contaminated with NDEA and unfit for human use.

15. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. According to the FDA, “[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity, and stability as brand-name drugs.”

16. Here, the valsartan-containing drugs manufactured by the Mylan Defendants are supposed to be equivalent to the brand-name drug, Diovan. However, they are not because they suffer from a manufacturing defect which caused the Mylan Defendants’ generic valsartan to be contaminated with NDEA.

17. As such, the Mylan Defendants’ valsartan-containing medications are neither safe nor of equal quality to the brand-name version of the medication.

18. Not only did the Mylan Defendants’ valsartan-containing medications fail to live up to FDA standards, but the Mylan Defendants falsely boast the quality and efficacy of their medications on their website, in their packaging, and other materials presented to the consumer, which were relied upon by Plaintiff Cacaccio and class members in deciding to purchase their valsartan-containing medication from the Mylan Defendants.

² <https://www.reuters.com/article/us-health-valsartan/cost-of-blood-pressure-drug-surges-in-u-s-after-recall-idUSKCN1MQ2X8> (last visited 12/4/18).

19. For example, the Mylan Defendants boast on their website:

Mylan applies one global quality standard across our facilities, and across our product line ... regardless of market.

At Mylan, whether it's a medication for millions or for a handful of people our priorities are to meet or exceed industry standards.

Because there's nothing generic about our standards. **Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made.** In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.

To us, trust goes beyond our global quality standards. It's all about caring for the people who will be helped by what we do.

Quality is at the heart of everything we do.³

20. These warranties by the Mylan Defendants are false. An internal review should have caught the manufacturing defect that caused their medications to be contaminated with NDEA, but it did not. In fact, it took over four months for the Mylan Defendants to issue a voluntary recall after the initial wave of recalls was announced. It took an additional two weeks for the Mylan Defendants to finally issue a full recall of all non-expired lots of its valsartan-containing medication on December 4, 2018.

21. The representations made by the Mylan Defendants regarding the quality of their medications was a material misrepresentation that was relied upon by Plaintiff and Class Members.

22. Moreover, the Mylan Defendants make the following additional representations:

Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries.

³ <http://www.mylan.com/en/products/quality> (last visited 12/4/18).

Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.⁴

23. These representations are also false, as the Mylan Defendants' valsartan API is contaminated with carcinogenic NDEA, which testing should have revealed.

24. Shortly before the voluntary recall was announced by the FDA on November 20, 2018, the FDA issued a Warning Letter to Mylan, "summariz[ing] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals."⁵

25. The documented regulatory violations included failure to "clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, **quality, or purity** of the drug product beyond the official or other established requirements." (Emphasis added). Further, Mylan failed to "follow written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and to record and justify any deviations from them."

26. The FDA noted in its letter that Mylan has committed multiple similar violations at multiple sites. The FDA stated:

FDA cited similar CGMP violations at this and other facilities in your company's network. Since 2015, FDA has taken the following actions in response to CGMP violations at Mylan facilities.

- On August 6, 2015, three Mylan facilities (FEI No. 3003813519, FEI No. 3007512701, and FEI No. 3007648351) were issued a combined Warning Letter for, among other things, inadequate

⁴ <http://www.mylan.com/en/products/active-pharmaceutical-ingredients> (last visited 12/4/18).

⁵ <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm626360.htm> (last visited 12/4/18).

controls for manufacturing sterile drugs; failure to establish scientifically sound and appropriate laboratory controls; and failure to thoroughly investigate unexplained discrepancies.

• On April 3, 2017, Mylan Laboratories, Ltd., FEI No. 3005587313, was issued a Warning Letter for, among other things, invalidating numerous initial OOS assay results without sufficient investigations to determine the root cause of the initial failure.

27. Because of these repeat and uncorrected violations, the FDA recommended that Mylan engage an independent third party CGMP consultant.

Plaintiff Cacaccio and Class Members were harmed by purchasing and consuming contaminated valsartan-containing medications manufactured, distributed, and sold by Defendants.

28. Plaintiff and the Class were injured by the full purchase price of their valsartan-containing medications. These medications are worthless, as they are contaminated with carcinogenic and harmful NDEA, and therefore are not fit for human consumption. Indeed, Plaintiff has been instructed to immediately stop using the medication, and has been instructed to return the remaining medication for another, non-contaminated brand. Plaintiff and the Class are further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDEA, and for damages related to Defendants' conduct.

29. Plaintiff brings this action on behalf of himself and Class Members 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) unjust enrichment; (vi) fraudulent concealment; (vii) fraud; (viii) conversion; (ix) strict products liability; (x) gross negligence; (xi) negligence; and (xii) battery.

PARTIES

30. Plaintiff Joseph Cacaccio is a citizen of New York who resides in Levittown, New

York. During all relevant time periods, Plaintiff Joseph Cacaccio was prescribed, purchased, and consumed valsartan-containing medication manufactured and distributed by Defendants Mylan and Mylan N.V., and sold by Defendant Rite Aid. Plaintiff Cacaccio originally learned about the valsartan recall by receiving a letter dated November 23, 2018 from Defendant Rite Aid, which informed him that Mylan and Mylan N.V. were recalling his medication “due to trace amounts of an impurity, N-nitrosodeethylamine (NDEA) contained in an active pharmaceutical ingredient (API) in Valsartan, USP manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial process, and has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC).” Further investigation revealed that Plaintiff Cacaccio has been using the contaminated valsartan manufactured and distributed by Mylan and Mylan N.V. for some time. When purchasing his valsartan-containing medications from Defendants Mylan, Mylan N.V., and Rite Aid, Plaintiff Cacaccio 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 and free from contaminants and defects. Plaintiff Cacaccio relied on these representations and warranties in deciding to purchase his valsartan-containing medications from Defendants Mylan, Mylan N.V., and Rite Aid, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased his valsartan-containing medications from Defendants Mylan, Mylan M.V., and Rite Aid if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Cacaccio also understood that in making the sale, Rite Aid was acting with the knowledge and approval of Mylan and Mylan N.V. and/or as the agent of Mylan and Mylan N.V. Plaintiff Cacaccio also understood that each purchase involved a direct

transaction between himself and Mylan and Mylan N.V., because his medication came with packaging and other materials prepared by Mylan and Mylan N.V., including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

31. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Defendant Mylan Pharmaceuticals, Inc. conducts substantial business in the State of New York, and nationwide. Defendant Mylan Pharmaceuticals, Inc. has been engaged in the manufacturing, sale, and distribution of contaminated generic valsartan in the United States, including in New York. Defendant Mylan Pharmaceuticals, Inc. is, upon information and belief, the United States subsidiary of Mylan N.V. Defendant Mylan Pharmaceuticals, Inc. acts as the agent and alter ego of Mylan N.V.

32. Defendant Mylan N.V. is a global generic and specialty pharmaceuticals company registered in the Netherlands, with its global headquarters at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Defendant Mylan N.V. conducts substantial business in New York, and nationwide. Defendant Mylan N.V. has been engaged in the manufacturing, sale, and distribution of contaminated generic valsartan in the United States, including in the State of New York. Upon information and belief, Mylan N.V. is the parent company of U.S.-based Mylan Pharmaceuticals, Inc.

33. Defendant Rite Aid Corporation is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Defendant Rite Aid Corporation sells the Mylan Defendants' valsartan-containing medication throughout the United States, and specifically in the State of New York.

Plaintiff Joseph Cacaccio purchased his valsartan-containing medication at a Rite Aid location in Levittown, New York.

JURISDICTION AND VENUE

34. This 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 (the “Class”), 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.

35. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, Plaintiff resides 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 contaminated valsartan-containing medications in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

36. Plaintiff seeks to represent a class defined as all persons in the United States who purchased or paid for valsartan-containing medications that are contaminated with NDEA (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 venturers, 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.

37. Plaintiff Cacaccio also seeks to represent a subclass of all Class members who purchased valsartan-containing medications in New York (the "New York Subclass").

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

39. **Numerosity.** The members of the Class are geographically dispersed throughout the United States 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. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member who was prescribed the contaminated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the contaminated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

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

(a) whether the valsartan-containing medications manufactured, distributed, and sold by Defendants were in fact contaminated with NDEA, thereby breaching the express and implied warranties made by Defendants and making the medication unfit for human consumption and

therefore unfit for their intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence, as well as battery as to the victims of the contaminated medication;

(b) whether Defendants knew or should have known that the valsartan-containing medications were in fact contaminated with NDEA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence, and negligence per se;

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

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

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

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

(g) whether Defendants are liable to Plaintiff and the Class for breaches of express and implied warranties;

(h) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;

(i) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

(j) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and

(k) whether the marketing, advertising, packaging, labeling, and other promotional materials for Defendants' valsartan-containing medications are deceptive.

41. **Typicality.** Plaintiff's claims are typical of the claims of the other members of

the Class in that Defendants mass marketed and sold contaminated medications to consumers throughout the United States. This contamination was present in all of the recalled medications manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiff and Class members by manufacturing, distributing, and selling the contaminated valsartan medication. Plaintiff's claims are typical in that all Class Members were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to Plaintiff.

42. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class. 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. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.

43. **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 members is 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, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class 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.

44. In the alternative, the Class may also be certified because:

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

(b) the prosecution of separate actions by individual Class 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 members 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 the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

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

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

46. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Subclass against Defendants.

47. Plaintiff, and each member of the nationwide Class, formed a contract with Defendants at the time Plaintiff and the other Class members purchased the contaminated valsartan medications. The terms of the contract include the promises and affirmations of fact

made by Defendants on the contaminated medication's packaging and through marketing and advertising, including that the product would be of the same quality and equally as safe as the brand-name version of the medication. 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 Defendants.

48. Defendants further expressly warranted that the valsartan-containing medications would contain only what was stated on the label, and would not contain harmful and carcinogenic defects and impurities such as NDEA. Plaintiff relied on the express warranty that his medication would contain only what was stated on the label, and that it would not be contaminated with impurities. These express warranties further formed the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

49. Defendants purport, through their advertising, labeling, marketing and packaging to create an express warranty that the medication would be of the same quality and of equal safety as the name-brand medication.

50. Plaintiff and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the contaminated medication.

51. Defendants breached express warranties about the contaminated medication and their qualities because Defendants' statements about the contaminated medications were false and the contaminated medication does not conform to Defendants' affirmations and promises described above.

52. Plaintiff and each of the members of the Class would not have purchased the contaminated medication had they known the true nature of the contaminated medication's

ingredients and what the contaminated medication contained (*i.e.*, NDEA).

53. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class have been damaged in the amount of the purchase price of the Product and any consequential damages resulting from the purchases.

54. On December 4, 2018, 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. Plaintiff's 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 Plaintiff's counsel's letter is attached hereto as **Exhibit A**.

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

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

56. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the Subclass against Defendants.

57. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the valsartan-containing medications (i) contained no NDEA and (ii) are generally recognized as safe for human consumption.

58. Defendants breached the warranty implied in the contract for the sale of the contaminated valsartan-containing medications because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the

valsartan-containing medications manufactured, distributed, and sold by Defendants were contaminated with carcinogenic NDEA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

59. Plaintiff and Class members purchased the valsartan-containing medications in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

60. The valsartan-containing medications were not altered by Plaintiff or Class members.

61. The valsartan-containing medications were defective when they left the exclusive control of Defendants.

62. Defendants knew that the valsartan-containing medications would be purchased and used without additional testing by Plaintiff and Class members.

63. The contaminated valsartan medication was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class members did not receive the goods as warranted.

64. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class members have been injured and harmed because: (a) they would not have purchased the valsartan-containing medication on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) the valsartan-containing medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

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

67. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

68. 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.

69. Plaintiff and members of the Subclass are consumers who purchased products from Defendants for their personal use.

70. 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 valsartan-containing medications (i) contained no NDEA or other harmful impurities; and (ii) are generally recognized as safe for human consumption.

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

72. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the valsartan-containing medications manufactured, distributed, and sold by Defendants to induce consumers to purchase the same.

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

of New York's General Business Law.

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

75. As a result of Defendants' violations, Plaintiff and members of the Subclass have suffered damages because: (a) they would not have purchased Defendants' valsartan-containing medications on the same terms if they knew that the products contained NDEA, and are not generally recognized as safe for human consumption; and (b) Defendants' valsartan products do not have the characteristics, ingredients, uses, or benefits promised.

76. On behalf of himself and other members of the Subclass, Plaintiff and the Subclass seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

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

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

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

79. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of the New York GBL.

80. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

81. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, have resulted in consumer injury or harm to the public interest.

82. Plaintiff and members of the New York Subclass have been injured because: (a) they would not have purchased the contaminated valsartan-containing medication if they had known that the medications contained carcinogenic NDEA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDEA. As a result, Plaintiff and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

83. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to the Misrepresentations, Plaintiff has suffered and will continue to suffer economic injury.

84. Plaintiff and members of the New York Subclass suffered an ascertainable loss caused by Defendants' Misrepresentations because they paid more for the medications than they would have had they known the truth about the Products (i.e. the full purchase price).

85. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to enjoin the unlawful acts and practices described herein, to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Unjust Enrichment
(On Behalf Of The Nationwide Class)

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 Subclass against Defendants.

88. Plaintiff and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' contaminated valsartan medication.

89. Defendants voluntarily accepted and retained this benefit.

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

COUNT VI
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

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

92. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

93. Defendants had a duty to disclose material facts to Plaintiff and the Class given their relationship as contracting parties and intended users of the medication. Defendants also had a duty to disclose material facts to Plaintiff and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and contaminated medications unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

94. Defendants possessed knowledge of these material facts. In fact, Defendants failed to announce a recall for over four months after the initial recall of valsartan medications was announced, and failed to effectuate a full recall until two weeks after their initial recall of only fifteen (15) lots of the medication. Further, reports from government agencies reveal that

this contamination may date as far back as 2012. During the time that Defendants concealed the contamination, Plaintiff and Class members were using the medication without knowing it contained the harmful impurity NDEA. In fact, Plaintiff was switched to the Mylan Defendants' valsartan medication from another recalled brand, under the mistaken belief that it was safe for human use, when in fact it was not.

95. Defendants failed to discharge their duty to disclose these material facts.

96. In so failing to disclose these material facts to Plaintiff and the Class, Defendants intended to hide from Plaintiff and the Class that they were purchasing and consuming medications with harmful impurities that were unfit for human use, and thus acted with scienter and/or an intent to defraud. As discussed above, Defendants obtained a substantial financial benefit as a result of their fraudulent concealment of the contaminated nature of the medication.

97. Plaintiff and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the contaminated valsartan medication manufactured, distributed, and sold by Defendants had they known it was contaminated with NDEA.

98. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class suffered damages in the amount of monies paid for the defective medication.

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

COUNT VII
Fraud
(On Behalf Of The Nationwide Class)

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

101. Plaintiff brings this claim individually and on behalf of the members of the

proposed Class and Subclass against Defendants.

102. As discussed above, Defendants provided Plaintiff and Class members with false or misleading material information about the valsartan medications manufactured, distributed, and sold by Defendants. For example, the Mylan Defendants boast on their website:

Mylan applies one global quality standard across our facilities, and across our product line ... regardless of market.

At Mylan, whether it's a medication for millions or for a handful of people our priorities are to meet or exceed industry standards.

Because there's nothing generic about our standards. **Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made.** In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.

To us, trust goes beyond our global quality standards. It's all about caring for the people who will be helped by what we do.

Quality is at the heart of everything we do.

And

Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries.

Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.

103. As indicated above, however, these representations are false as its valsartan medications were contaminated with carcinogenic NDEA.

104. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase these contaminated valsartan-

containing medications.

105. Defendants knew that the medications contained these harmful impurities, but continued to manufacture them, even after other manufacturers from India voluntarily recalled their products. In fact, reports from government agencies reveal that this contamination can date back to 2012. During that time that Defendants knew of but failed to disclose the contamination, Plaintiff and Class Members were using the medication without knowing it contained the harmful impurity NDEA.

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

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

COUNT VIII
Conversion
(On Behalf Of The Nationwide Class)

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

109. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

110. Plaintiff and the Class have an ownership right to the monies paid for the contaminated medication manufactured, distributed, and sold by Defendants.

111. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the contaminated medication. Defendants have done so every time that Plaintiff and the Class have paid to have their prescriptions filled.

112. As a direct and proximate cause of Defendants' conversion, Plaintiff and the

Class suffered damages in the amount of the payments made for each time they filled their prescriptions.

COUNT IX
Strict Liability – Manufacturing Defect
(On Behalf Of The Nationwide Class)

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

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

115. The NDEA impurity contained in the Defendants' medications was a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurity NDEA. NDEA was not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.

116. Due to the NDEA impurity, the product was not reasonably safe as marketed because NDEA is a known carcinogen, and, according to the FDA, the level of NDEA in the effected medication far exceeded acceptable levels, warranting an immediate recall of the effected medication.

117. NDEA is acutely toxic and therefore immediately causes injury when ingested.

118. Plaintiff and all Class members used the product for its intended purpose, meaning they used the product as prescribed by their respective doctors.

119. There is no way that Plaintiff or Class members could have discovered the defect by exercising reasonable care. There was no way for Plaintiff or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact contaminated with NDEA. Nothing short of laboratory tests (which should have been done by Defendants for

quality control purposes) would have revealed the defect to the unsuspecting consumer.

120. Because Plaintiff and Class members had no way of knowing that their medication was in fact contaminated, Plaintiff and Class members could not have avoided the injury by exercising ordinary care.

121. Defendants were supposed to manufacture, distribute, and sell valsartan-containing medications without any harmful impurities such as NDEA. The valsartan medications were not designed or intended to contain NDEA. These impurities resulted from a manufacturing defect which allowed the medication to become contaminated.

122. Plaintiff and Class Members suffered harm as a result of consuming this contaminated medication. The ingestion of NDEA is acutely harmful. NDEA, when ingested orally, is immediately harmful to the liver, kidneys, and pulmonary function. “Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.” As such, NDEA causes harm as soon as it is consumed.

123. Importantly, Plaintiff and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

124. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a manufacturing defect which caused Plaintiff and Class members an immediate and concrete harm, Defendants are strictly liable to Plaintiff and Class Members.

COUNT X
Gross Negligence
(On Behalf Of The Nationwide Class)

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

126. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

127. Defendants owed a duty of care to Plaintiff to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

128. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

129. Plaintiff and Class members were injured by ingesting an acutely toxic substance, to wit NDEA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants. Plaintiff and Class members also suffered economic damages and emotional distress from the purchase and use of the valsartan-containing medications.

130. Importantly, Plaintiff and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiff and Class members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

131. For the reasons set forth at length above, Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

132. Because the valsartan medications manufactured, distributed, and sold by

Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiff and Class members, and because Defendants failed to act promptly to remediate the harmful impurity, Defendants are grossly negligent and are liable to Plaintiff and Class members for all injuries proximately caused by Defendants' gross negligence.

COUNT XI
Negligence
(On Behalf Of The Nationwide Class)

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

134. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

135. Defendants owed a duty of care to Plaintiff and Class members to manufacture, distribute, and sell the subject valsartan medications free from harmful defects and impurities.

136. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDEA.

137. Plaintiff and Class members were injured by ingesting an acutely toxic substance, to wit NDEA, which was negligently present in the valsartan medications manufactured, distributed, and sold by Defendants.

138. Importantly, Plaintiff and the Class members do not seek resolution of downstream effects of NDEA such as cancer or other individualized illnesses on a class-wide basis. Any such actions can and should be redressed on an individual basis as they arise. However, because of the acute toxicity of NDEA, Plaintiff and Class members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

139. Because the valsartan medications manufactured, distributed, and sold by

Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiff and Class members, Defendants are negligent and are liable to Plaintiff for all injuries proximately caused by Defendants' negligence.

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

141. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

142. The Mylan Defendants owed a duty to Plaintiff and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to the brand name Diovan and/or complied with cGMPs and/or was not adulterated or contaminated.

143. The Mylan Defendants owed a duty to Plaintiff and the Class because New York, and every other State, territory, and possession has adopted and/or adheres to federal cGMP and adulteration standards.

144. The Mylan Defendants failed to comply with federal cGMPs and/or federal adulteration standards.

145. As a result of the Mylan Defendants' failures to do so, the Mylan Defendants own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

146. As a direct and proximate result of the Mylan Defendants' negligent conduct, Plaintiff and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

COUNT XII
Battery
(On Behalf Of The Nationwide Class)

147. Plaintiff hereby incorporates by reference the allegations contained in all

preceding paragraphs of this complaint.

148. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendants.

149. Defendants manufactured, distributed, and sold the contaminated valsartan medication to Plaintiff and Class members with the knowledge and intent that Plaintiff and Class members would ingest the medication. Defendants thus had knowledge that the harmful medication would come into contact with the bodies of Plaintiff and Class members.

150. The intended contact, i.e. the medication being ingested by Plaintiff, was harmful in nature because the medication contained the harmful impurity NDEA.

151. As such, Defendants committed an unlawful battery on Plaintiff and Class members, who ingested the medication.

PRAYER FOR RELIEF

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

- A. For an order certifying the nationwide Class and the Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as representative of the Class and Subclass and Plaintiff's attorneys as Class Counsel to represent the Class and members of the Subclass;
- B. For an order declaring the Defendants' conduct violates the statutes referenced herein;
- C. For an order finding in favor of Plaintiff, the nationwide Class, and the 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;

- G. For injunctive relief as pleaded or as the Court may deem proper; and
- H. For an order awarding Plaintiff and the Class and 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: December 5, 2018

Respectfully submitted,

BURSOR & FISHER, P.A.

By: /s/ Scott A. Bursor
Scott A. Bursor

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EXHIBIT A



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ndeckant@bursor.com

December 4, 2018

Via Certified Mail – Return Receipt Requested

Mylan Pharmaceuticals, Inc.
1000 Mylan Boulevard
Canonsburg, PA 15317

Mylan N.V.
1000 Mylan Boulevard
Canonsburg, PA 15317

Rite Aid Corporation
30 Hunter Lane
Camp Hill, PA 17011

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Mylan Pharmaceuticals, Inc., Mylan N.V., and Rite Aid Corporation pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties related to our client, Joseph Cacaccio, and a class of all similarly situated purchasers (the “Class”) of contaminated valsartan-containing medication manufactured, distributed, and sold by Mylan Pharmaceuticals, Inc., Mylan N.V., and Rite Aid Corporation.

Our client was prescribed and purchased valsartan-containing medication manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V., and sold by Rite Aid Corporation. Our client’s valsartan-containing medications were contaminated with N-nitrosodiethylamine (NDEA), a carcinogenic and liver-damaging impurity. On November 20, 2018, the U.S. Food & Drug Administration announced a voluntary recall of fifteen (15) lots of valsartan-containing generic medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V. The recall was due to the presence of NDEA in the recalled products. This defect rendered the products unusable and unfit for human consumption. In short, the valsartan-containing medications that our client and the Class was purchasing are worthless, as they contained a toxic impurity rendering them unfit for human use. Mylan Pharmaceuticals, Inc., Mylan N.V., and Rite Aid Corporation each violated express and implied warranties made to our client and the Class regarding the quality and safety of the valsartan-containing medications they purchased. *See* U.C.C. §§ 2-313, 2-314.

On behalf of our client and the Class, we hereby demand that Mylan Pharmaceuticals, Inc., Mylan N.V., and Rite Aid Corporation immediately (1) cease and desist from continuing to sell contaminated valsartan-containing medications and (2) make full restitution to all purchasers of the contaminated valsartan-containing medications of all purchase money obtained from sales thereof.

We also demand that Mylan Pharmaceuticals, Inc., Mylan N.V., and Rite Aid Corporation preserve all documents and other evidence which refer or relate 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 Mylan Pharmaceuticals, Inc. and Mylan N.V.'s valsartan-containing medications;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of valsartan-containing medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V.;
3. All tests of the valsartan-containing medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V.;
4. All documents concerning the pricing, advertising, marketing, and/or sale of valsartan-containing medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V.;
5. All communications with customers involving complaints or comments concerning the valsartan-containing medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V.;
6. All documents concerning communications with any retailer involved in the marketing or sale of valsartan-containing medications manufactured and distributed by Mylan Pharmaceuticals, Inc. and Mylan N.V.;
7. All documents concerning communications with federal or state regulators; and
8. All documents concerning the total revenue derived from sales of valsartan-containing medication.

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,



Neal J. Deckant