UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ELIZABETH DUFFY and JOHN DUFFY, on behalf of themselves and all others similarly situated, Plaintiffs, v. SOLCO HEALTHCARE U.S., LLC, PRINSTON PHARMACEUTICAL, INC., WALGREEN CO. a/k/a WALGREENS, and THROGGS NECK PHARMACY, Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Elizabeth Duffy and John Duffy ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendants Solco Healthcare U.S., LLC ("Solco"), Prinston Pharmaceutical, Inc. ("Prinston"), Walgreen Co. a/k/a Walgreens ("Walgreens"), and Throggs Neck Pharmacy (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 Defendants Solco and Prinston's manufacturing and distribution of valsartan-containing generic prescription medications contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. In turn, Defendants Walgreens and Throggs Neck Pharmacy sold this contaminated generic medication to Plaintiffs and other similarly situated consumers.

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 overseas laboratories in China, certain generic formulations have become contaminated with NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens." While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA, such as through the contaminated valsartan medications, can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall of several brands of valsartan-containing generic medications, including those manufactured and distributed by Defendants Solco and Prinston. The recall was due to the presence of NDMA in the recalled 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." The FDA is "investigating the levels of NDMA in the recalled products, assessing the possible effect on patients who have been taking them and [determining] what measures can be taken to reduce or eliminate the impurity from future batches produced by the company."

5. 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. Defendant Solco, who is in the business of marketing and distributing generic pharmaceuticals, explains on its website:

> Generic pharmaceuticals are **identical (bioequivalent)** to the branded medications with regard to:
>
> - Intended use
> - Effectiveness
> - Dosage form
> - Strength
> - **Safety**
> - Route of administration
> - **Quality**

Defendant Solco's website further explains:

> Our products are **manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements**. Solco is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products. Together we strive to offer greater access to affordable medications that **you can trust**.

6. However, each of these representations and warranties made by Solco are false. To the contrary, Solco's valsartan-containing medications are neither safe nor of "high quality." In fact, the European Medicines Agency explained that "NDMA is an unexpected impurity that was not detected by routine tests carried out by [Solco and Prinston's parent company in China,] Zhejiang Huahai," and that the change in the manufacturing process which led to the impurity was introduced in 2012 and is "believed to have produced NDMA as a side product." As such, this contamination has likely existed for approximately six years without being detected.

7. Plaintiffs 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 NDMA and are not fit for human consumption. Indeed, Plaintiffs have been instructed to immediately stop using the medication, and have turned in their remaining medication for another, non-contaminated brand. 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.

8. Plaintiffs bring this action on behalf of the Class 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, 350; (iv) unjust enrichment, (v) fraudulent concealment, (vi) fraud, (vii) conversion, (viii) strict products liability, (ix) gross negligence, (x) negligence, and (xi) battery.

PARTIES

9. Plaintiff Elizabeth Duffy is a citizen of New York who resides in the Bronx, New York. During all relevant time periods, Plaintiff Elizabeth Duffy was prescribed valsartan-containing medication, which she purchased from Defendant Throggs Neck Pharmacy, and was manufactured and distributed by Defendants Solco and Prinston. Plaintiff Elizabeth Duffy originally learned about the valsartan recall by searching the Internet. After reading about the recall online, she promptly called her pharmacy, Throggs Neck Pharmacy. A staff member at Throggs Neck Pharmacy verified Plaintiff Elizabeth Duffy's prescription and instructed her to immediately turn in her prescription for a new one, and indicated that Plaintiff Elizabeth Duffy's prescription was contaminated and subject to the FDA's recall. Further investigation revealed that Plaintiff Elizabeth Duffy has been using the contaminated valsartan distributed by Prinston and Solco for some time. When purchasing her valsartan-containing medications from

Defendants Solco, Prinston, and Throggs Neck Pharmacy, Plaintiff Elizabeth Duffy 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 Elizabeth Duffy relied on these representations and warranties in deciding to purchase her valsartan-containing medications from Defendants Solco, Prinston, and Throggs Neck Pharmacy, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her valsartan-containing medications from Defendants Solco, Prinston, and Throggs Neck Pharmacy if she had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff Elizabeth Duffy also understood that in making the sale, Throggs Neck Pharmacy was acting with the knowledge and approval of Solco and Prinston and/or as the agent of Solco and Prinston. Plaintiff Elizabeth Duffy also understood that each purchase involved a direct transaction between herself and Solco and Prinston, because her medication came with packaging and other materials prepared by Solco and Prinston, including representations and warranties that her medications were properly manufactured and free from contaminants and defects.

10. Plaintiff John Duffy is a citizen of New York who resides in Nyack, New York. During all relevant time periods, Plaintiff John Duffy was prescribed valsartan-containing medication, which he purchased from Defendant Walgreens in Nyack, New York. Plaintiff John Duffy received a letter from Defendant Walgreens via U.S. Mail advising him that the valsartan-containing medication he was taking was affected by the recall. When purchasing his valsartan-containing medications from Defendants Solco, Prinston, and Walgreens, Plaintiff John Duffy reviewed the accompanying labels and disclosures, and understood them as representations and

warranties by both the manufacturer and pharmacy that the medications were properly manufactured and free from contaminants and defects. Plaintiff John Duffy relied on these representations and warranties in deciding to purchase his valsartan-containing medications from Defendants Solco, Prinston, and Walgreens, 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 Solco, Prinston, and Walgreens if he had known that they were not, in fact, properly manufactured and free from contaminants and defects. Plaintiff John Duffy also understood that in making the sale, Walgreens was acting with the knowledge and approval of Solco and Prinston and/or as the agent of Solco and Prinston. Plaintiff John Duffy also understood that each purchase involved a direct transaction between himself and Solco and Prinston, because his medication came with packaging and other materials prepared by Solco and Prinston, including representations and warranties that his medications were properly manufactured and free from contaminants and defects.

11. Defendant Solco Healthcare U.S., LLC ("Solco") is a limited liability company organized under the laws of the State of Delaware and maintains its principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512. Defendant Solco conducts substantial business in the State of New York. Defendant Solco boasts on its website that it "is an industry leader in marketing and distributing generic pharmaceuticals," and that it "currently markets 38 products," which "are manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements." Defendant Solco's website further states that it is "a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products …. Together we strive to offer

greater access to affordable medications that you can trust."

12. Defendant Prinston Pharmaceutical, Inc. ("Prinston") is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Defendant Prinston conducts substantial business in the State of New York. Defendant Prinston explains on its website that "[Defendant] Solco Healthcare U.S. is the U.S. sales and marketing division of Prinston Pharmaceutical Inc."

13. Defendant Walgreens is a corporation organized under the laws of the State of Illinois and maintains its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Defendant Walgreens conducts substantial business in the State of New York. Plaintiff John Duffy purchased his valsartan-containing medication at a Walgreens location in Nyack, New York.

14. Defendant Throggs Neck Pharmacy is, upon information and belief, a corporation organized under the laws of the State of New York and maintains its principal place of business at 3569 E. Tremont Ave, Bronx, NY 10465. Among other services, Throggs Neck Pharmacy provides pharmacy services. Defendant Throggs Neck Pharmacy conducts substantial business in the State of New York. Plaintiff Elizabeth Duffy purchased her valsartan-containing medication at Throggs Neck Pharmacy in the Bronx, New York.

JURISDICTION AND VENUE

15. 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.

16. 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, Plaintiffs reside 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

17. Plaintiffs seek to represent a class defined as all persons in the United States who purchased valsartan-containing medications that are contaminated with NDMA (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.

18. Plaintiffs also seek to represent a subclass of all Class members who purchased valsartan-containing medications in New York (the "New York Subclass").

19. 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.

20. **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, Plaintiffs reasonably estimate that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiffs, 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.

21. **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 NDMA, 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 NDMA prior to the recall, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

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

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

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

(f) whether Defendants are liable to Plaintiff and the Class for violation of the New York General Business Law §§ 349 & 350, *et seq.*;

(g) whether Defendants are liable to Plaintiffs for breaches of express and implied warranty;

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

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

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

(k) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive;

22. **Typicality.** Plaintiffs' 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 Plaintiffs and Class members by manufacturing, distributing, and selling the contaminated valsartan medication. Plaintiffs' claims are typical in that they were uniformly harmed in purchasing and consuming the contaminated medications. Plaintiffs' claims are further typical in that Defendants deceived Plaintiffs 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 Plaintiffs.

23. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Class. 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. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

24. **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.

25. 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)

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

27. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

28. Plaintiffs, and each member of the nationwide Class, formed a contract with Defendants at the time Plaintiffs 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 "quality" and "safe." 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 Defendants.

29. 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 NDMA. Plaintiffs relied on the express warranty

that their 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 Plaintiffs and the members of the Class and Defendants.

30. Defendants purport, through their advertising, labeling, marketing and packaging to create an express warranty that the medication would be of the same "quality" and the "bioequivalent" of the name-brand medication, and that it would be "safe."

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

32. 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.

33. Plaintiffs 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.*, NDMA).

34. As a result of Defendants' breaches of express warranty, Plaintiffs 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.

35. On August 14, 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. 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 Nationwide Class)

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

37. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

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

39. 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 and liver toxic NDMA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiffs and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

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

41. The valsartan-containing medications were not altered by Plaintiffs or Class members.

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

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

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

45. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiffs 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 NDMA, 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)

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

47. Plaintiffs bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

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

49. 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.

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

51. 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 NDMA or other harmful impurities; and (ii) are generally recognized as safe for human consumption.

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

53. 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.

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

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

56. As a result of Defendants' violations, Plaintiffs 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 NDMA, 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.

57. On behalf of themselves and other members of the Subclass, Plaintiffs 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)

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

59. Plaintiffs bring this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

60. 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.

61. Defendants' false, misleading, and deceptive statements and representations of fact, including but not limited to, that the medication was safe and was not tainted with harmful impurities such as NDMA ("the Misrepresentations"), were and are directed to consumers.

62. 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.

63. 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.

64. Plaintiffs 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 liver-toxic and carcinogenic NDMA; and (b) the medications do not have the characteristics, uses, or benefits as promised, namely that the medications were contaminated with NDMA. As a result, Plaintiffs and members of the New York Subclass have been damaged in the full amount of the purchase price of the medications.

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

66. Plaintiffs 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).

67. On behalf of themselves and other members of the New York Subclass, Plaintiffs seek to enjoin the unlawful acts and practices described herein, to recover their 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)

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

69. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

70. Plaintiffs and the Class conferred a benefit on Defendants in the form of monies

paid to purchase Defendants' contaminated valsartan medication.

71. Defendants voluntarily accepted and retained this benefit.

72. 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)

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

74. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

75. Defendants had a duty to disclose material facts to Plaintiffs 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 Plaintiffs 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.

76. Defendants possessed knowledge of these material facts. In fact, reports from government agencies reveal that this contamination may date back to 2012. Defendants therefore withheld the knowledge of the contamination for nearly six years before finally disclosing the issue in July 2018. During that time, Plaintiffs and Class members were using the medication without knowing it contained the harmful impurity NDMA.

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

78. In so failing to disclose these material facts to Plaintiffs and the Class, Defendants intended to hide from Plaintiffs 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.

79. Plaintiffs 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 NDMA.

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

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

COUNT VII
Fraud
(On Behalf Of The Nationwide Class)

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

83. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

84. As discussed above, Defendants provided Plaintiffs and Class members with false or misleading material information about the valsartan medications manufactured, distributed, and sold by Defendants, including but not limited to Defendant Solco's statement that:

> Generic pharmaceuticals are **identical (bioequivalent)** to the branded medications with regard to:
>
> - Intended use
> - Effectiveness
> - Dosage form

- Strength
- **Safety**
- Route of administration
- **Quality**

Defendant Solco further represented and warranted that:

> Our products are **manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements**. Solco is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical , leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosage products. Together we strive to offer greater access to affordable medications that **you can trust**.

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

86. Defendants knew that the medications contained these harmful impurities, but continued to manufacture them for nearly six years until finally reporting the issue. In fact, reports from government agencies reveal that this contamination can date back to 2012. Defendants therefore withheld the knowledge of the contamination for nearly six years before finally disclosing the issue. During that time, Plaintiffs and Class Members were using the medication without knowing it contained the harmful impurity NDMA.

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

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

COUNT VIII
Conversion
(On Behalf Of The Nationwide Class)

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

90. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants

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

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

93. As a direct and proximate cause of Defendants' conversion, Plaintiffs 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)

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

95. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

96. The NDMA impurity contained in the Defendants' medications was a mishap in the manufacturing process which led to the valsartan medications containing the harmful impurity NDMA. NDMA was not intended to be included in the medication; it was an impurity

that was created due to an error in the manufacturing process.

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

98. The effected medication was recalled in 22 other countries around the world, in addition to the United States.

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

100. There is no way that Plaintiffs or Class members could have discovered the defect by exercising reasonable care. There was no way for Plaintiffs or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact contaminated with NDMA. 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.

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

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

103. Plaintiffs and class members suffered harm as a result of consuming this contaminated medication. The ingestion of NDMA is acutely harmful. NDMA, when ingested

orally, is immediately harmful to the liver, kidneys, and pulmonary function. Animal studies confirm that acute exposure of NDMA "demonstrated that [NDMA] has high to extreme acute toxicity from inhalation or **oral exposure**." "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, NDMA causes harm as soon as it is consumed.

104. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDMA such as cancer, jaundice, and 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 NDMA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

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

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

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

107. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

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

109. Defendants breached that duty by manufacturing, distributing, and selling

valsartan medication contaminated with NDMA.

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

111. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDMA such as cancer, jaundice, and 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 NDMA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

112. As this defective condition traces back to 2012, with nearly six years between when the defect arose and any action was taken, Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

113. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiffs and Class members, and because Defendants failed to act to remediate the harmful impurity for nearly six years, Defendants are grossly negligent and are liable to Plaintiffs for all injuries proximately caused by Defendants' gross negligence.

COUNT XI
Negligence
(On Behalf Of The Nationwide Class)

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

115. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

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

117. Defendants breached that duty by manufacturing, distributing, and selling valsartan medication contaminated with NDMA.

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

119. Importantly, Plaintiffs and the Class members do not seek resolution of downstream effects of NDMA such as cancer, jaundice, and 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 NDMA, Plaintiffs and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis.

120. Because the valsartan medications manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiffs and class members, Defendants are negligent and are liable to Plaintiffs for all injuries proximately caused by Defendants' negligence.

COUNT XII
Battery
(On Behalf Of The Nationwide Class)

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

122. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

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

124. The intended contact, i.e. the medication being ingested by Plaintiffs, was harmful in nature because the medication contained the harmful impurity NDMA.

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

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 nationwide Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class and New York Subclass and Plaintiffs' attorneys as Class Counsel to represent the Class and New York Subclass members;

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

C. For an order finding in favor of Plaintiffs, the nationwide Class, and the New York 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 Plaintiffs and the Class and New York 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), Plaintiffs demand a trial by jury of any and all issues in this action so triable of right.

Dated: August 14, 2018

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Neal J. Deckant*
Neal J. Deckant

Neal J. Deckant
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EXHIBIT A

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August 14, 2018

Via Certified Mail – Return Receipt Requested

Solco Healthcare U.S., LLC
2002 Eastpark Boulevard, Suite A
Cranbury, New Jersey 08512

Prinston Pharmaceutical, Inc.
2002 Eastpark Boulevard
Cranbury, New Jersey 08512

Walgreen Co. a/k/a Walgreens
200 Wilmot Road
Deerfield, Illinois 60015

Throggs Neck Pharmacy
3569 E. Tremont Avenue
Bronx, NY 10465

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 Solco Healthcare U.S., LLC ("Solco"), Prinston Pharmaceutical, Inc. ("Prinston"), Walgreen Co. a/k/a Walgreens ("Walgreens"), and Throggs Neck Pharmacy pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties related to our clients, Elizabeth Duffy and John Duffy, and a class of all similarly situated purchasers (the "Class") of contaminated valsartan-containing medication.

Our clients were prescribed and purchased valsartan-containing medication manufactured and distributed by Solco and Prinston, and sold by Walgreens and Throggs Neck Pharmacy. Our clients' respective valsartan-containing medications were contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. On July 13, 2018, the U.S. Food & Drug Administration announced a voluntary recall of several brands of valsartan-containing generic medications, including those manufactured and distributed by Solco and Prinston. The recall was due to the presence of NDMA in the recalled products. This defect rendered the products unusable and unfit for human consumption. In short, the valsartan-containing medications that our clients and the Class were purchasing are worthless, as they contained a toxic impurity rendering them unfit for human use. Solco, Prinston, Walgreens, and

Throggs Neck Pharmacy each violated express and implied warranties made to our clients 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 clients and the Class, we hereby demand that Solco, Prinston, Walgreens, and Throggs Neck Pharmacy 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 Solco, Prinston, Walgreens, and Throggs Neck Pharmacy 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 valsartan-containing medications from Solco and Prinston;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of valsartan-containing medications manufactured and distributed by Solco and Prinston;

3. All tests of the valsartan-containing medications manufactured and distributed by Solco and Prinston;

4. All documents concerning the pricing, advertising, marketing, and/or sale of valsartan-containing medications manufactured and distributed by Solco and Prinston;

5. All communications with customers involving complaints or comments concerning the valsartan-containing medications manufactured and distributed by Solco and Prinston;

6. All documents concerning communications with any retailer involved in the marketing or sale of valsartan-containing medications manufactured and distributed by Solco and Prinston;

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 manufactured and distributed by Solco and Priston.

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