IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

ALPHONSE BORKOWSKI, Individually and on behalf of all others similarly situated,
4030 Autumnway Lane
Hamburg, NY 14075,

Plaintiff,

v.

PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC
2002 Eastpark Boulevard
Cranbury, NJ 08512,

SOLCO HEALTHCARE U.S. , LLC
2002 Eastpark Boulevard
Cranbury, NJ 08512,

HUAHAI US INC.
2002 Eastpark Boulevard
Cranbury, NJ 08512,

Defendants.

Civil Action No.:_____

Jury Trial Demanded

Complaint-Class Action

CLASS ACTION COMPLAINT

Plaintiff Alphonse Borkowski ("Plaintiff"), individually and on behalf of all others similarly situated, brings this action against Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC and Solco Healthcare U.S., LLC (together "Solco"), and Huahai US Inc. ("Huahai US"). Plaintiff's allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Plaintiff brings this nationwide and New York class individually on behalf of the Class and Subclass defined below of hundreds of thousands of other consumers who paid for Defendants' generic Valsartan ("Valsartan") that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA").

2. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and otherwise the same as brand Diovan®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at the Zhejiang Huahai Pharmaceuticals ("ZHP") manufacturing plant in China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA and/or other impurities.

4. These adulterated Valsartan drugs were introduced into the American market at least as far back as 2015 by Defendants who profited from their sale to American consumers, such as Plaintiff and Class Members. However, evidence now suggests that the contamination dates back at least as far as 2012. Plaintiff and Class Members paid for all or part of their Valsartan

prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. PARTIES

5. Plaintiff Alphonse Borkowski is a New York resident. During the class period, he paid money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Borkowski that their respective generic Valsartan products were the same as brand Diovan. Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Borkowski would not have paid for Defendants' Valsartan products.

6. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Prinston is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

7. Defendant Solco Healthcare U.S., LLC ("Solco U.S.") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Defendant Solco is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Solco U.S. has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

8. Defendant Huahai US Inc. ("Huahai US") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

Defendant Huahai US is a subsidiary of Huahai Pharmaceutical. At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

III. JURISDICTION AND VENUE

9. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action. In addition, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

10. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in New York, and otherwise intentionally avail themselves of the markets within New York through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

11. Venue is proper in this District because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2), and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Valsartan Background

12. Valsartan is a potent, orally active nonpeptide tetrazole derivative which, when ingested, causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

13. Valsartan is the generic version of the registered listed drug ("RLD") DIOVAN® ("Diovan"), which was marked in tablet form by Novartis AG ("Novartis") beginning in July 2001

upon approval by the U.S. Food and Drug Administration ("FDA").

14. Diovan was an immensely popular drug. Globally, Diovan generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States.

15. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product.

16. Although Novartis's Diovan patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. <u>The Generic Drug Approval Framework</u>

17. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

18. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

19. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

20. The bioequivalence basis for ANDA approval is premised on the generally accepted

proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

21. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

22. And finally, a generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

23. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of it generic products.

24. According to the FDA, there are fifteen Abbreviated New Drug Applications

("ANDAs") approved for generic Diovan, *i.e.*, Valsartan.

C. Background on Current Good Manufacturing Practices ("cGMPs")

25. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

26. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

27. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. §351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacting laws adopting or mirroring these federal standards.

28. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out

prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

29. Indeed FDA regulations require a "quality control unit" to independently test drug products manufactured by another company on contract:

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

21 C.F.R. § 211.22(a).

D. <u>The Zhejiang Huahai Pharmaceuticals ("ZHP") Manufacturing Facilities</u>

30. Zhejiang Huahai Pharmaceuticals ("ZHP") is a subsidiary of Huahai Pharmaceutical, which is also the corporate parent of Defendants Prinston, Huahai US, and Solco. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities is located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and European Union.

31. ZHP serves as a contract manufacturer of Defendants' Valsartan products, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above.

32. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

33. On or about March 27-30, 2007, the FDA inspected ZHP's Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the

facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

34. On May 15-19, 2017, FDA again inspected ZHP's Linhai City facilities. That inspection resulted the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

35. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. These are disturbing signs of systematic data manipulation designed to intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

36. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and black metallic particles found in API batches.

E. Defendants Were Aware of Potential NDMA Contamination As Early As 2012

37. Upon information and belief, ZHP changed its Valsartan manufacturing processes in or about 2012, if not earlier.

38. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed

as a side product after Zhejiang Huahai introduced changes to its manufacturing process in 2012."[1]

39. NDMA is yellow, oily liquid with a faint, characteristic odor and a sweet taste, and is often produced as a by-product of industrial manufacturing processes.

40. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

41. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a "B2" rating, meaning that it is "probably carcinogenic to humans" with little or no human data.

42. Anecdotally, NDMA has also been used in intentional poisonings.[2]

43. Most assuredly, NDMA is not an FDA-approved ingredient for branded Diovan or generic Valsartan. None of Defendants' Valsartan products (or any Valsartan product, for that matter) identifies NDMA as an ingredient on the products' labels or elsewhere.

44. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

45. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality

[1] *See* European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, *at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1 (last accessed Aug. 31, 2018).

[2] *See* Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/ (last accessed Aug. 31, 2018).

> control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

46. And as reproduced above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

47. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants and ZHP, the NDMA contamination in Defendants' Valsartan products would have been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their Valsartan products were adulterated as early as 2012.

48. However, there are indications that Defendants and ZHP had actual knowledge of Valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

49. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing" and routinely disregarded sampling anomalies suggestive of impurities.

50. These discoveries by the FDA's investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

51. Defendants were also specifically aware of the manufacturing issues at ZHP based on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's

inspections of ZHP's facilities in March 2007 and May 2017.

52. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical, and Solco was specifically aware or should be imputed with actual knowledge of ZHP's willful deviations from cGMPs. Solco and Huahai US have offices in the same office building in Cranbury, New Jersey.

53. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their Valsartan products only after the FDA had threatened an involuntary recall.

F. FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan

54. On or about July 13, 2018, the FDA announced voluntary recalls by Defendants and other manufacturers for their Valsartan products manufactured by ZHP.[3] The recall is for products distributed as early as October 2015. However, as alleged above, it is likely that Defendants' Valsartan manufactured 2012 and beyond was also contaminated with NDMA.

55. On or about July 27, 2018, the FDA announced expanded recalls of additional Valsartan products manufactured by Defendants and non-parties, and re-packaged by third parties.[4]

56. As stated in the FDA's July 13, 2018 statement:

> The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an

[3] FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, *at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm (last accessed Aug. 31, 2018).
[4] FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, *at* https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Aug. 31, 2018).

> impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. 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.

G. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

57. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

58. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[5] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

59. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

60. By introducing their respective Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan and with the FDA-approved

[5] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Aug. 31, 2018).

label that is the same as that of Diovan, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with Diovan.

61. Furthermore, Defendant Solco states on its "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[6]

62. On the "Drug Safety" page of Solco's website, Solco states that "Solco Healthcare is committed in providing … its patients with high quality, FDA-approved generic medications."[7]

63. Defendant Solco lists its Valsartan products on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's Valsartan Prescribing Information.[8] Clicking the "Prescribing Information" link loads a .pdf of the Prescribing Information with a Solco URL address (http://www.solcohealthcare.com/uploads/product/info/valsartan-pi-artwork_170524_141555.pdf).

64. Each Defendant's Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic manufacturers of Valsartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

65. In addition, on information and belief, each Defendant affirmatively

[6] Solco, OVERVIEW, *at* http://solcohealthcare.com/about-solco.html (last accessed Aug. 31, 2018).
[7] Solco, TRADE PARTNER INFORMATION, *at* http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Aug. 31, 2018).
[8] Solco, VALSARTAN TABLETS, *at* http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last accessed Aug. 31, 2018).

misrepresented and warranted to consumers through their websites, brochures, and other marketing or informational materials that their Valsartan product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

66. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan and thus non-therapeutically interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan®, and breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not contained in Diovan®, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

67. At all relevant times, Defendants have also impliedly warranted that their Valsartan products were merchantable and/or fit for their ordinary purposes.

68. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence of NDMA in Defendants' Valsartan means that Defendants have violated implied warranties to Plaintiff and Class Members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' implied

warranty of merchantability and/or fitness for ordinary purposes.

69. For these and other reasons, Defendants' Valsartan is therefore adulterated and it was illegal for Defendants' to have introduced such Valsartan for sale and distribution in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

70. Adulterated Valsartan is essentially worthless. No consumer would knowingly purchase an adulterated Valsartan product. Indeed, the purchase of adulterated Valsartan product is not allowed because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

H. New Revelations Continue to Unfold About Other Manufacturing Plants

71. The recall of Defendants' Valsartan products is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other Valsartan products manufactured at another plant in India, and by other non-parties. *See supra* n.4. On August 20, 2018 the FDA announced that it was going to test all Valsartan products for NDMA.[9] Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

I. Fraudulent Concealment and Tolling

72. Plaintiff and Class Members causes of action accrued on the date the FDA announced the recall of Defendants' generic Valsartan products.

73. Alternatively, any statute of limitation or prescriptive period is equitably tolled due to Defendants' fraudulent concealment. Defendants each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid

[9] FDA Statement, STATEMENT FROM FDA COMMISSIONER, *at* http://freepdfhosting.com/1c7e5ed26e.pdf (last accessed Aug. 31, 2018).

disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

74. For instance, no Defendant revealed to the public that their Valsartan product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

75. To the contrary, each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

76. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[10]

77. Because of this, Plaintiff and other Class Members did not discover, nor would they discover through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

78. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other

[10] Huahai US, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, *at* https://www.huahaius.com/media.html (last accessed Aug. 31, 2018).

efforts, Plaintiff were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

J. Plaintiff Alphone Borkowski's Individual Facts

79. Plaintiff Alphonse Borkowski is a resident of Hamburg, New York.

80. On or about August 22, 2017, November 15, 2017, February 15, 2018, and May 14, 2018, Plaintiff Borkowski purchased generic Valsartan manufactured by the Solco Defendants and bearing NDC Number 43547-0315-09. On these occasions, Plaintiff Borkowski paid a co-pay of $3.00.

81. The generic Valsartan purchased by Plaintiff Borkowski manufactured by the Solco Defendants was not therapeutically equivalent to brand Diovan®, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

82. The Solco Defendants' generic Valsartan was sold illegally to Plaintiff Borkowski.

V. CLASS ACTION ALLEGATIONS

83. Plaintiff brings this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

> All individuals in the United States of America and its territories and possessions who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants.

84. In the alternative, Plaintiff alleges Sub-Classes for all individuals in each State, territory, or possession including specifically the State of New York who, since at least January 1, 2012, paid any amount of money out of pocket (for personal or household use) for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and

alternative state sub-classes are referred to as the "Class."

85. Excluded from the Class and Sub-Class[es] are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

86. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create further subclasses as the Court deems necessary.

87. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class and Sub-Class[es].

88. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of Valsartan consumers nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

89. **Commonality**: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiff and Class Members regarding Defendants' Valsartan products;

b. Whether each Defendant's Valsartan product was in fact the same as brand Diovan® consistent with such express or implied warranties;

c. Whether each Defendant's Valsartan product was contaminated with NDMA;

d. Whether each Defendant's Valsartan product containing NMDA was adulterated;

e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan products;

f. Whether each Defendant affirmatively misrepresented or omitted facts that its Valsartan product was the same as brand Diovan® and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs and/or was not adulterated;

h. Whether Plaintiff and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of damages;

i. Whether a common damages model can calculate damages on a classwide basis;

j. When Plaintiff's and Class Members' causes of action accrued;

k. Whether Defendants fraudulently concealed Plaintiff's and Class Members' causes of action.

90. **Typicality**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as all other Class Members.

91. **Adequacy of Representation**: Plaintiff is committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class action, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

92. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate as to the Class as a whole.

93. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiff. Plaintiff' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF THE CLASS AND SUB-CLASS[ES])

94. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

95. Each Defendant expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with brand Diovan®. In other words, Defendants expressly warranted that their products were the same as Diovan®.

96. Each Defendant sold Valsartan product that they expressly warranted were

compliant with cGMP and/or not adulterated.

97. Each Defendant's Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

98. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

99. At the time that each Defendant marketed and sold its Valsartan product, they

recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan®, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other Class Members.

100. Each Defendant breached its express warranties with respect to its Valsartan product as it was not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated.

101. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

SECOND CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

102. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

103. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann.

§ 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq*.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

104. Each Defendant was a merchant within the meaning of the above statutes.

105. Each Defendant's Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

106. Each Defendant was obligated to provide Plaintiff and other Class Members reasonably fit Valsartan product for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

107. Each Defendant knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan®, and impliedly warranted that same was of merchantable quality and fit for that purpose.

108. Each Defendant breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not

conform to the standards generally applicable to such goods.

109. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

THIRD CAUSE OF ACTION
FRAUD
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

110. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

111. Defendants affirmatively misrepresented material facts including, *inter alia*, that their Valsartan products were therapeutically equivalent to brand Diovan® and/or complied with cGMPs and/or were not adulterated.

112. Defendants failed to disclose material facts to render non-misleading its statements about, *inter alia*, that their Valsartan products were not therapeutically equivalent to brand Diovan® and/or did not comply with cGMPs and/or were adulterated.

113. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' Valsartan product – product which Defendants knew or should have known was not therapeutically equivalent to brand Diovan and/or did not comply with GMPs and/or were adulterated. Plaintiff and other Class Members would not have paid some or all of the amounts they paid for Defendants' Valsartan product had they known the truth.

114. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

115. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' Valsartan products.

116. Defendants' misrepresentations and omissions were material.

117. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiff and other Class Members to pay for Defendants' Valsartan product.

118. But for these misrepresentations and omissions, Plaintiff and other Class Members would have not have paid for Defendants' Valsartan product.

119. To the extent applicable, Plaintiff and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' Valsartan product but-for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

120. Plaintiff and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

FOURTH CAUSE OF ACTION
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349 ET SEQ.
(INDIVIDUALLY AND ON BEHALF OF THE NEW YORK SUB-CLASS)

121. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

122. Plaintiff and Defendants are "persons" under New York General Business Law § 349(h), and Defendants' conduct occurred in the course of trade or commerce.

123. Defendants' conduct constitutes a prohibited "[d]eceptive acts or practices in the

conduct of any business, trade, or commerce," N.Y. Gen. Bus. Law § 349.

124. Defendants have engaged in unfair, unlawful and deceptive acts in trade and commerce which have the capacity and tendency to deceive and, in fact, did deceive Plaintiff and the class, and damaged Plaintiff and class members.

125. Defendants affirmatively misrepresented (and/or wrongfully concealed and omitted) that their Valsartan products were therapeutically equivalent to brand Diovan and/or were manufactured in compliance with cGMPs and/or were not adulterated. In fact, Defendants' Valsartan products were contaminated with NDMA resulting in Defendants' Valsartan products not being therapeutically equivalent to brand Diovan and not manufactured in compliance with cGMPs and in fact constituting adulterated pharmaceuticals.

126. Defendants committed unlawful, deceptive, and unconscionable trade practices by marketing, selling, and otherwise placing into the stream of commerce Defendants' Valsartan products on the premise they were therapeutically equivalent to brand Diovan and/or manufactured in compliance with cGMPs and/or were not adulterated.

127. Defendants wrongfully concealed, suppressed, and omitted to disclose that its Valsartan products were not therapeutically equivalent to brand Diovan and/or not manufactured in compliance with cGMPs and/or were in fact adulterated.

128. Defendant's misrepresentations and omissions had the capacity to mislead Plaintiff and Class Members into believing (i) that Defendants' Valsartan Products were therapeutically equivalent to brand Diovan, (ii) were manufactured in accordance with cGMPs, and/or (iii) were not adulterated and were legal to sell in the United States when the opposite was true.

129. Had Defendants not made misrepresentations or not omitted such facts, Defendants' Valsartan products would not have been available to Plaintiff because, among other

reasons, it would have been illegal for Defendants to even introduce their Valsartan products into the United States. Plaintiff and the class members were injured as a result.

130. Because of Defendants' unlawful, deceptive, unfair, and unconscionable trade practices, Plaintiff and other members of the class have suffered injury and damages – an ascertainable loss – in an amount to be determined at trial. This court has the power to enjoin Defendants' conduct.

FIFTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS AND SUB-CLASS[ES])

131. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

132. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

zz. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

576. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

577. Each Plaintiff and other Class Member are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

578. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances.

579. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages in an amount – an ascertainable loss – to be proved at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS AND SUB-CLASS[ES])

133. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

134. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiff and other Class Members by virtue of the latter's paying for Defendants' Valsartan product.

135. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' Valsartan products were adulterated, their distribution and sale in the United States was illegal.

136. Plaintiff and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' Valsartan product. It would

be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiff and other Class Members as a result of their wrongful conduct alleged in this Complaint.

137. Plaintiff and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

SEVENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS AND SUB-CLASS[ES])

138. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

139. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

140. Each Defendant owed a duty to Plaintiff and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

141. Each Defendant owed a duty to care to Plaintiff and the Class because they were the foreseeable, reasonable, and probable user of Valsartan product and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its Valsartan product was not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

142. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own Valsartan product. Each Defendant knew that ignoring the

manufacturing issues surrounding its Valsartan product would damage Plaintiff and the Class and increase its own profits.

143. Each Defendant maintained or should have maintained a special relationship with Plaintiff and the Class, as they were obligated to ensure that its Valsartan product complied with cGMPs and/or was not adulterated.

144. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its Valsartan product.

145. Each Defendant breached the duties owed to Plaintiff and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the Class.

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

EIGHTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS AND SUB-CLASS[ES])

147. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.

148. Each Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacturing of its Valsartan product.

149. Each Defendant owed a duty to Plaintiff and the Class to ensure that the Valsartan product it sold in the United States was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

150. Each Defendant owed a duty to Plaintiff and the Class because each State, territory,

and possession has adopted and/or adheres to federal cGMP and adulteration standards.

151. Each Defendant failed to comply with federal cGMPs and/or federal adulteration standards.

152. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

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

JURY DEMAND

Plaintiff respectfully request a trial by jury on all causes of action so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff pray for the following judgment:

A. An Order certifying this Action as a class action;

B. An Order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A Declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

D. An Order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

E. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

Dated: October 19, 2018

RESPECTFULLY SUBMITTED,

/s/ Paul G. Joyce

Paul G. Joyce
COLUCCI & GALLAHER, P.C.
2000 Liberty Building
424 Main Street
Buffalo, New York 14202
Tel.: 716-853-4080
Fax: 716-853-4070
pjoyce@colucci-gallaher.com

Ruben Honik (PA Bar 33109)
(*pro hac vice* pending)
David Stanoch (PA Bar 91342)
(*pro hac vice* pending)
GOLOMB & HONIK, P.C.
1835 Market Street, Suite 2900
Philadelphia, PA 19103
Tel.: 215-965-9177
Fax: 215-985-4169
rhonik@golombhonik.com
dstanoch@golombhonik.com

Michael L. Slack (TX Bar 18476800)
(*pro hac vice* pending)
John R. Davis (TX Bar 24099518)
(*pro hac vice* pending)
SLACK DAVIS SANGER, LLP
2705 Bee Cave Road, Suite 220
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
mslack@slackdavis.com
jdavis@slackdavis.com

Allan Kanner (LA Bar 20580)
(*pro hac vice* pending)
Conlee S. Whiteley (LA Bar 22678)
(*pro hac vice* pending)
Layne Hilton (LA Bar 36990)
(*pro hac vice* pending)
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, Louisiana 70115
Tel.: 504-524-5777
Fax: 504-524-5763
a.kanner@kanner-law.com
c.whiteley@kanner-law.com
l.hilton@kanner-law.com

Counsel for Plaintiff and the Class

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of New York

Alphonse Borkowski, Individually and on behalf of all others similarly situated,

Plaintiff(s)

v.

PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC, SOLCO HEALTHCARE U.S., LLC, HUAHAI US, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC, SOLCO HEALTHCARE U.S., LLC, HUAHAI US, INC.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Paul G. Joyce, Esq., Colucci & Gallaher, P.C., 2000 Liberty Building, 424 Main Street, Buffalo, New York 14202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 10/19/2018

Signature of Clerk or Deputy Clerk

JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Alphonse Borkowski, Individually and on behalf of all others similarly situated,

(b) County of Residence of First Listed Plaintiff Erie
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Paul G. Joyce, Esq., Colucci & Gallaher, P.C.
2000 Liberty Building, 424 Main Street, Buffalo, NY 14202
(716) 853-4080 - SEE ATTACHMENT

DEFENDANTS

PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC, SOLCO HEALTHCARE U.S., LLC, HUAHAI US INC.,

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 862 Black Lung (923)	☐ 485 Telephone Consumer Protection Act
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 863 DIWC/DIWW (405(g))	☐ 490 Cable/Sat TV
☐ 196 Franchise				☐ 864 SSID Title XVI	☐ 850 Securities/Commodities/ Exchange
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application	FEDERAL TAX SUITS	☐ 891 Agricultural Acts
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 896 Arbitration
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			☐ 950 Constitutionality of State Statutes
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/19/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Paul G. Joyce, Esq.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____