IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

ERIC J. ERWIN, Individually and on behalf of all others similarly situated, Plaintiff, v. PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC, SOLCO HEALTHCARE U.S., LLC, HUAHAI US INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No.:_____ **Jury Trial Demanded** **Complaint-Class Action**

CLASS ACTION COMPLAINT

Plaintiff Eric Erwin ("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"), Huahai US Inc. ("Huahai US"), and Teva Pharmaceutical Industries, Ltd. ("Teva Pharmaceutical") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (together "Teva"). Plaintiff's allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Plaintiff brings this action on behalf of himself and hundreds of thousands of other Valsartan consumers who paid for Defendants' generic 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 for Defendants to profit 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 Eric Erwin is a Texas resident. During the class period, he paid money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff Erwin 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 Erwin 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.

9. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Pharmaceutical") is a foreign company incorporated and headquartered in Peta Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States.

10. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical. Teva USA on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Teva USA has been

engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States. Collectively, Teva Pharmaceutical and Teva USA are referred to as "Teva" herein.

III. JURISDICTION AND VENUE

11. 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.

12. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in New Jersey, and otherwise intentionally avails itself of the markets within New Jersey through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

13. Venue is proper in this District because: Defendants reside in this District, 28 U.S.C. § 1391(b)(1); 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

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

15. 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").

16. 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.

17. 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.

18. 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>

19. 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).

20. 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.*

21. 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).

22. 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.

23. 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).

24. 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).

25. 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.

26. 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")

27. 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).

28. 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.

29. 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.

30. 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.

31. Indeed FDA regulations require a "quality control unit" to independently test drug product 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>

32. 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.

33. ZHP serves as a contract manufacturer of Defendants' Valsartan products (including Defendant Teva's Valsartan products), and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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

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

40. 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]

41. 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.

42. 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).

43. 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.

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

45. 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.

46. 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

[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).

assurance obligations, Defendants would have found the NDMA contamination almost immediately.

47. 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 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).

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

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical, and Solco was specifically aware 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.

55. 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

56. 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.

[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).

57. 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]

58. 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 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

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

60. 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,

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[4] FDA News Release, FDA UPDATES ON VALSARTAN RECALLS, *at* https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Aug. 31, 2018).

[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).

Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

61. 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.

62. 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 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.

63. 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]

64. 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]

65. 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).

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[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).

66. Defendant Teva has a "Generics FAQs" on its website.[9] In response to the question "Are generic drugs safe?" Defendant Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

67. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Defendant Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

68. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

69. 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.

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

[9] Teva, PRODUCTS, *at* http://www.tevapharm.com/our_products/generic_qa/ (last accessed Aug. 31, 2018).

(or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

71. 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 gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not also 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.

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

73. 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.

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

75. Adulterated Valsartan is essentially worthless. No consumer would purchase an adulterated Valsartan product or is even allowed to purchase adulterated Valsartan product 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

76. 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 product 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.[10] 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

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

78. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact

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

that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

79. 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.

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

81. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[11]

82. 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.

83. 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

[11] 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 Eric Erin's Individual Facts

84. Plaintiff Eric Erwin is a resident of Frisco, Texas.

85. On or about March 16, 2017 and June 15, 2017, Plaintiff Erwin purchased generic Valsartan manufactured by the Solco Defendants and bearing NDC Number 43547-0369-09. On these occasions, Plaintiff Erwin paid a co-pay of $20.64 and $19.67.

86. The generic Valsartan purchased by Plaintiff Erwin 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.

87. The Solco Defendants' generic Valsartan was sold illegally to Plaintiff Erwin.

88. On or about August 1, 2017, November 13, 2017, January 20, 2018, and May 10, 2018, Plaintiff Erwin purchased generic Amlodipine-Valsartan manufactured by the Teva Defendants and bearing NDC Number 00093-7690-56 or 65862-0737-30 (the May 10, 2018 purchase). Plaintiff Erwin paid copays of $55.72, $37.42, $36.03, and $36.03, respectively.

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

90. The Teva Defendants' generic Valsartan was sold illegally to Plaintiff Erwin.

K. Extraterritorial Application of New Jersey and Pennsylvania Law as to Solco and Teva Defendants, Respectively

91. As alleged above, the Solco Defendants named herein maintain their corporate headquarters in New Jersey and the Teva Defendants maintain their corporate headquarters in

Pennsylvania.

92. The express and implied warranties alleged herein were made from and originated from Defendants' respective headquarters in New Jersey and Pennsylvania, respectively.

93. The mispresentations and/or material omissions regarding the therapeutic equivalence of the Defendants' Valsartan products to brand Diovan, and regarding the Defendants' cGMP violations and/or distribution of adulterated Valsartan in the United States were made from the Defendants' New Jersey and Pennsylvania headquarters, respectively.

94. Plaintiff intends to seek additional discovery to show that Defendants' warranties and breach thereof, and violations of consumer protection statutes, and other breaches of common law occurred and emanated primarily from New Jersey in the case of the Solco Defendants and Pennsylvania in the case of the Teva Defendants, or otherwise as discovery shall demonstrate.

V. CLASS ACTION ALLEGATIONS

95. 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.

96. In the alternative, Plaintiff alleges sub-classes for all individuals in each State, territory, or possession who, since at least January 1, 2012, paid any amount of money out of pocket for Valsartan product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative state sub-classes are referred to as the "Class."

97. Excluded from the Class 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.

98. Plaintiff reserve the right to narrow or expand the foregoing class definition, or to create subclasses as the Court deems necessary.

99. Plaintiff meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

100. **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.

101. **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 their generic 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.

102. **Typicality**: Plaintiff' claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff have 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.

103. **Adequacy of Representation**: Plaintiff are 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 have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

104. 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 respecting the Class as a whole.

105. The elements of Rule 23(b)(3) are met. 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)

106. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

107. 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.

108. Each Defendant sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

109. 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.

110. 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.

111. 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.

112. 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.

113. 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)

114. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

115. 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.

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

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

118. 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.

119. 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.

120. 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.

121. 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)

122. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

123. 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.

124. 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.

125. 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.

126. 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.

127. 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.

128. Defendants' misrepresentations and omissions were material.

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

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

131. 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.

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

FOURTH CAUSE OF ACTION AGAINST SOLCO DEFENDANTS
VIOLATION OF NEW JERSEY CONSUMER FRAUD ACT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

133. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein. This claim is asserted on a nationwide basis against the Solco and Huahai US Defendants only. A state-specific New Jersey subclass is likewise asserted against the Teva Defendants *infra*.

134. Plaintiff and other members of the class are "persons" within the meaning of *N.J.S.A.* 56:8-1(d).

135. Defendant's conduct alleged herein constitutes a "sale" within the meaning of *N.J.S.A.* 56:8-1(e).

136. The New Jersey Consumer Fraud Act ("NJCFA") declares unlawful "[t]he act, use

or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby[.]" *N.J.S.A.* 56:8-2.

137. 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.

138. 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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. Pursuant to the NJCFA, this court has the power to enjoin Defendants' conduct.

144. Furthermore, the Court should find that the NJCFA applies extraterritorially because Defendants' conduct and violations of the NJCFA was orchestrated from and out of New Jersey. For instance, Defendants' personnel responsible for ensuring cGMP compliance are based in New Jersey; Defendants' personnel who executed quality agreements with ZHP are located in New Jersey; Defendants' personnel who maintain or oversee those who maintain Defendants' websites and other marketing materials are located in New Jersey.

FIFTH CAUSE OF ACTION AGAINST TEVA DEFENDANTS
VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW ("UTPCPL"), 73 P.S. § 201-1, ET SEQ. (INDIVIDUALLY AND ON BEHALF OF THE CLASS)

145. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein. This claim is asserted on a nationwide basis against the Teva Defendants only. A state-specific Pennsylvania subclass is likewise asserted against the Solco Defendants *infra*.

146. The UTPCPL, 73 P.S. § 201-3 prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

147. The Teva Defendants have engaged in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce by:

a) "Causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services," *see* 73 P.S. § 201-2(4)(ii);

b) "Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another," *see* 73 P.S. § 201-2(4)(iii);

c) "Using deceptive representations . . . in connection with goods or services," *see* 73 P.S. § 201-2(4)(iv);

d) "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have," *see* 73 P.S. § 201-2(4)(v);

e) "Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another," *see* 73 P.S. § 201-2(4)(vii);

f) "Advertising goods or services with intent not to sell them as advertised," *see* 73 P.S. § 201-2(4)(ix);

g) "Failing to comply with the terms of any written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made," *see* 73 P.S. § 201-2(4)(xiv); and/or,

h) "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding," *see* 73 P.S. § 201-2(4)(xxi).

148. Defendants violated the above provisions through the conduct alleged herein.

149. Pursuant to 73 P.S. § 201-9.2, *et seq*., Plaintiff and Class Members purchased Defendants' generic Valsartan products primarily for personal, family, or household purposes.

150. Defendants' conduct violating the UTPCPL was done knowingly, intentionally, and/or recklessly.

151. To the extent applicable, Plaintiff and Class Members relied on the Defendants' mispresentations and material omissions regarding their generic Valsartan products. Further, to the extent applicable, reliance can be assumed under the circumstances for reasons including but not limited to the fact that Defendants could not have legally sold their adulterated generic Valsartan products in the United States but for their misrepresentations and material omissions. Plaintiff and Class Members would not and could not have purchased Defendants' generic Valsartan products but for the alleged violations of the UTPCPL. To the extent applicable, reliance may be presumed in these circumstances.

152. Plaintiff and Class Members suffered ascertainable damages as a result of Defendants' conduct. As redress, Plaintiff and Class Members are entitled to damages, declaratory relief, and any other relief the Court deems necessary.

SIXTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

153. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

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

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

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

or practices in violation of Mich. Stat. § 445.901, *et seq.*;

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

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

y. 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.*;

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

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

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

cc. 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.*;

dd. 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.*;

ee. 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.*;

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

gg. 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.*;

hh. 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.*;

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

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

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

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

mm. 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.*;

nn. 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.*;

oo. 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.*;

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

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

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

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

or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

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

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

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

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

xx. 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.

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

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

157. 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.

158. 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.

SEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

159. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

160. 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.

161. 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.

162. 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.

163. 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.

EIGHTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

164. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

165. 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.

166. 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.

167. 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.

168. 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.

169. 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.

170. 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.

171. 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.

172. 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.

NINTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

173. Plaintiff re-allege and incorporate the preceding paragraphs as if fully set forth herein.

174. 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.

175. 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.

176. 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.

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

178. 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.

179. 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: August 31, 2018

RESPECTFULLY SUBMITTED,

Counsel for Plaintiff and the Class

JS 44 (Rev. 06/17)

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

Eric J. Erwin

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

(c) [redacted]

DEFENDANTS

Prinston Pharmaceuticals, Inc d/b/a Solco Healthcare LLC; Solco Healthcare LLC, et al.

County of Residence of First Listed Defendant Middlesex
(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
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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)***:
28 U.S.C. Section 1332

Brief description of cause:
Fraudulent sale of adulterated product.

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 5,000,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 08/31/2018

SIGNATURE OF ATTORNEY OF RECORD [redacted]

FOR OFFICE USE ONLY

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

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.