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

PAULETTE SILBERMAN, Individually and on behalf of all others similarly situated, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.; HUAHAI US INC.; PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC; SOLCO HEALTHCARE U.S., LLC; TEVA PHARMACEUTICAL INDUSTRIES LTD.; ACTAVIS LLC; TEVA PHARMACEUTICALS USA, INC.; CARDINAL HEALTH, INC.; THE HARVARD DRUG GROUP, L.L.C.; MAJOR PHARMACEUTICALS, INC.; ARROW PHARM (MALTA) LTD.; ACTAVIS PHARMA, INC.; TORRENT PRIVATE LIMITED; TORRENT PHARMACEUTICALS, LTD.; TORRENT PHARMA, INC.; AUROBINDO PHARMA, LIMITED; AUROBINDO PHARMA USA, INC.; AUROLIFE PHARMA LLC; AND JOHN DOES 1-100, Defendants.	Civil Action No.:_____ **Jury Trial Demanded** **Complaint-Class Action**

1. Plaintiff Paulette Silberman ("Plaintiff"), individually and on behalf of all others similarly situated, brings this action against Zhejiang Huahai Pharmaceuticals Co., Ltd. ("ZHP"), Huahai US Inc. ("Huahai US"), Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston"), Solco Healthcare U.S., LLC ("Solco"), Teva Pharmaceutical Industries Ltd. ("Teva"), Actavis LLC ("Actavis"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Cardinal Health, Inc. ("Cardinal"), The Harvard Drug Group, L.L.C. ("Harvard"), Major Pharmaceuticals, Inc. ("Major"), Arrow Pharm (Malta) Ltd. ("Arrow"), Actavis Pharma, Inc. ("Actavis Pharma"),

Torrent Private Limited ("Torrent Private"), Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals"), Torrent Pharma, Inc. ("Torrent Pharma") (ZHP, Huahai US, Prinston, Solco, Teva, Actavis, Teva USA, Cardinal, Harvard, Major, Arrow, Actavis Pharma, Torrent Private, Torrent Pharmaceuticals, and Torrent Pharma, collectively, "ZHP Defendants"), Aurobindo Pharma, Limited ("Aurobindo"), Aurobindo Pharma USA, Inc. ("Aurobindo USA"), Aurolife Pharma LLC ("Aurolife") (Aurobindo, Aurobindo USA, and Aurolife, collectively, "Aurobindo Defendants"), and John Does 1-100 ("John Does") (ZHP Defendants, Aurobindo Defendants, and John Does, collectively, "Defendants"). Plaintiff's allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

2. Plaintiff brings this action on behalf of herself and other Valsartan consumers who consumed Defendants' generic Valsartan that was contaminated with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), and/or an IARC- and EPA-listed probable human carcinogen known as N-nitrosodiethylamine ("NDEA"), and who suffered cellular damage, genetic harm, developed cancer, and/or are at an increased risk of developing cancer as a result, but have not yet been diagnosed with cancer. Plaintiff seeks injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, including but not limited to notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment of cancer resulting, at least in part, from the exposure to the NDMA or NDEA contamination.

3. 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 the brand name medication, DIOVAN® ("Diovan"), were otherwise fit for

their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

4. However, for years, ZHP wrongfully manufactured ZHP Defendants' Valsartan products in a manner that they were contaminated with NDMA and NDEA as a result of ZHP's failure to manufacture the Valsartan Active Pharmaceutical Ingredient ("API") in a safe manner. On information and belief, ZHP changed its manufacturing process and/or introduced chemicals into the manufacturing process, without due care or tests, leading to the creation of NMDA and NDEA, which contaminated the Valsartan. ZHP Defendants negligently and willfully ignored warning signs regarding the operating standards at the ZHP manufacturing facilities in Linhai City, Zhejiang Province, China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after ZHP Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA, NDEA, and/or other impurities.

5. ZHP and Huahai US[1] sold ZHP's contaminated Valsartan API to at least four distribution chains: one containing Prinston and Solco; the second comprising Teva and Actavis; the third composed of Teva, Teva USA, Cardinal, Harvard, Major, Arrow, and Actavis Pharma; and the fourth consisting of Torrent Private, Torrent Pharmaceuticals, and Torrent Pharma.

6. Additionally, Aurobindo wrongfully manufactured Aurobindo Defendants' Valsartan products in a manner that they were contaminated with NDEA as a result of Aurobindo's failure to manufacture the Valsartan API in a safe manner. Aurobindo Defendants negligently and willfully ignored warning signs regarding the operating standards at the Aurobindo manufacturing

[1] "Huahai US Inc. is a subsidiary of Zhejiang Huahai Pharmaceutical Ltd., Co., focusing on the sales and marketing of APIs and Intermediates." Huahai US, HOMEPAGE, https://www.huahaius.com/index.html (last visited Apr. 5, 2019).

facilities in India, and continued to allow Aurobindo to manufacture their Valsartan products for sale to consumers in the United States even after Aurobindo Defendants knew or should have known that their Valsartan products manufactured by Aurobindo contained or likely contained NDEA and/or other impurities.

7. Aurobindo sold its contaminated Valsartan API to at least two distribution chains: the first containing Aurobindo USA, and the second comprising Aurobindo USA and Aurolife.

8. These contaminated, adulterated Valsartan drugs were introduced into the American market potentially as far back as November 2011 by Defendants. Plaintiff and other Class Members were exposed to highly dangerous and potentially fatal carcinogenic substances because they consumed Defendants' contaminated Valsartan. Defendants' conduct constitutes negligence, breach of express warranty, breach of implied warranty, defective manufacture, failure to warn, and other violations of state law.

II. PARTIES

9. Plaintiff is a New Jersey resident. During the class period, she consumed one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff that their respective generic Valsartan products were the same as the brand name medication Diovan. Had the truth about the contaminants within Defendants' products been made known, Plaintiff Silberman would not have consumed Defendants' Valsartan products. At all relevant times, there were adequate alternative medications and therapies available to Plaintiff.

A. ZHP Defendants

10. ZHP is based on investigation, information, and belief, a corporation in China, located at Xunqiao, Linhai City, Zhejiang Province, 317024. ZHP also has a United States headquarters located at 2009 Eastpark Boulevard, Cranbury, New Jersey 08512. At all times relevant to this case, ZHP has been a manufacturer of the contaminated Valsartan API at issue in

this Complaint, and has been involved in and/or responsible in whole or in part, for the distribution, sales, and marketing of the contaminated Valsartan in finished form both directly and through its subsidiaries, affiliates, and other purchasers.

11. Huahai US is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Huahai US is a wholly-owned subsidiary of ZHP. At all times material to this case, Huahai US has been engaged in the manufacture, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

12. Prinston is a Delaware corporation with its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Prinston is a majority-owned subsidiary of ZHP. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

13. Solco is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Solco is a wholly-owned subsidiary of Prinston and ZHP. At all times material to this case, Solco has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

14. Teva is a foreign company incorporated in Peta Tikvah, Israel, and headquartered at 5 Basel Street, Petach Tikva, Israel, 49131. 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 contaminated Valsartan in the United States, including in the State of New Jersey.

15. Actavis is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

16. Teva USA is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, and is Teva's wholly owned subsidiary. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

17. Cardinal is an Ohio corporation with its principal place of business at 7000 Cardinal Place, Dublin, Ohio 43017. At all times material to this case, Cardinal has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

18. Harvard is a Michigan limited liability company with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. It is a wholly-owned subsidiary of Cardinal. At all times material to this case, Harvard has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

19. Major is a corporation with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. Major is a wholly-owned subsidiary of Harvard. At all times material to this case, Major has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

20. Arrow is a foreign corporation headquartered at HF62 HalFar Industrial Estate, HalFar, BBG 300, Malta. Teva owns the entirety of Arrow, which on its own and/or through its parent company and subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Arrow has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

21. Actavis Pharma is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva's wholly owned subsidiary. At all times material to this case, Actavis Pharma has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

22. Torrent Private is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent Private 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, Torrent Private has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

23. Torrent Pharmaceuticals is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Over seventy percent of Torrent Pharmaceuticals is owned by Torrent Private. Torrent Pharmaceuticals 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, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

24. Torrent Pharma is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is a wholly-owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

B. Aurobindo Defendants

25. Aurobindo is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo 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, Aurobindo has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

26. Aurobindo USA is a Delaware corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. It is a wholly-owned subsidiary of Aurobindo. At all times material to this case, Aurobindo USA has been engaged in the manufacturing, sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

27. Aurolife is a Delaware limited liability company with its principal place of business at 2400 US- 130, North, Dayton, New Jersey 08810. It is a wholly-owned subsidiary of Aurobindo USA. At all times material to this case, Aurobindo USA has been engaged in the manufacturing,

sale, and distribution of contaminated Valsartan in the United States, including in the State of New Jersey.

28. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1 through 100, inclusive, are unknown to Plaintiff at this time. Plaintiff therefore sues these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiff as alleged below, and each John Doe is liable to the Plaintiff for the acts and omissions alleged below as well as the resulting damages sustained by the Plaintiff. Plaintiff will amend this Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

29. At all times relevant to this Complaint, each of the John Does was the agent, servant, employee, affiliate, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe acted in the full course, scope, and authority of that agency, service, employment, and/or joint venture.

III. JURISDICTION AND VENUE

30. 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.

31. This Court has personal jurisdiction over Defendants because Plaintiff resides in and consumed the Valsartan at issue in New Jersey, as did other Class Members, and because Defendants have sufficient minimum contacts in and with New Jersey, and otherwise intentionally

availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

32. 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

33. Valsartan is a medication which is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

34. Valsartan is the generic name of the registered listed drug ("RLD") Diovan, which was marketed in tablet form by Novartis International AG ("Novartis") beginning in July 2001 upon approval by the U.S. Food and Drug Administration ("FDA").

35. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA and NDEA are not FDA-approved ingredients of Diovan. Nor is NDMA or NDEA an FDA-approved ingredient of any generic Valsartan product. Nor does any label known to Plaintiff include NDMA or NDEA as an ingredient. NDMA and NDEA are unintended environmental contaminants and recognized carcinogens.

36. 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. The Generic Drug Approval Framework

37. 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).

38. 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*.

39. 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 RLD. Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

40. 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 determined to be safe and effective for the approved indication through 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 is assumed to be safe and effective for the same approved indication as the RLD.

41. 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).

42. 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).

43. 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 this through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of its generic products.

44. According to the FDA, there are approximately fifteen ANDAs approved for generic Diovan, *i.e.*, Valsartan.

C. Background on Current Good Manufacturing Practices

45. 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).

46. 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 with regard to a facility that is manufacturing drugs intended to be distributed in the United States.

47. 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 enacted laws adopting or mirroring these federal standards.

48. 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.

49. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

50. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

51. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and

assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

52. Additionally, a "quality control unit" must independently test drug products manufactured by another company on contract:

> 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. ZHP's Linhai City Facilities Before the Recall

53. ZHP has API manufacturing facilities 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 ZHP remains one of China's largest exporters of pharmaceuticals to the United States and European Union.

54. ZHP manufactures Valsartan for each ZHP Defendant, and ZHP Defendants thus have quality assurance obligations with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

55. 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.

56. On or about March 27-30, 2007, the FDA inspected ZHP's facility at Xunqiao in Linhai City, Zhejiang Province, China. That inspection revealed "deviations" from cGMPs.

57. The FDA inspected ZHP's the same facility again on November 14-18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

58. On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its Valsartan at this Chuannan facility. That inspection resulted in 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. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated."

59. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting an appropriate scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment." This practice was part of a pattern and practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA and NDEA. The May 2017 inspection also resulted in a finding that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product." This was based upon observations including the FDA's finding that equipment 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 were in API batches.

E. Aurobindo's Hyderabad Facilities Before the Recall

60. Aurobindo has API manufacturing facilities located in Hyderabad, Telangana, India.

61. Aurobindo manufactures Valsartan for each Aurobindo Defendant at these facilities, and Aurobindo Defendants thus have quality assurance obligations with respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

62. Aurobindo has a history of a deviations from FDA's cGMP standards.

63. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]nvestigations are inadequate." The FDA explained that Aurobindo failed to initiate stability testing, and "[t]he deviation record contains field 'Number of previous deviations in this product/system.' This field requires previous deviations of the same product or deviation type to be reported, no previous deviations were reported in this field." Moreover, "[t]his is a repeat observation from the 2014 inspection."

64. Three months later, the FDA returned to Aurobindo's Hyderabad facilities and found four noteworthy manufacturing problems. First, "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Second, "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform [sic] to appropriate standards of identity, strength, quality and purity." Third, "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are

represented to possess." Last, the "use of instruments and recording devises not meeting establishes specifications was observed."

65. In October 2016, the FDA observed that Aurobindo's nearby Borpatla facility had inadequately validated equipment cleaning procedures.

66. In April 2017, the FDA observed that the manufacturing equipment in Aurobindo's Hyderabad facilities "is not always maintained to achieve its intended purposes." "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." "[C]orrective and preventative actions (CAPAs), identified and initiated because of out of specifications (OOS) laboratory investigations, do not correlate to the identified root cause. In certain cases, CAPAs are not initiated at all." "Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established."

67. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second, "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

68. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions." Second, "[e]quipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." Third, "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." Fourth, "[b]uildings used in manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds[,] insects, and other vermin." Fifth, "[p]rocedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance." Sixth, "[e]mployees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions." Seventh, the "statistical quality control criteria fail to include appropriate acceptance levels and rejection levels." Eighth, "[e]stablished laboratory control mechanisms are not followed and documented at the time of performance." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."

F. <u>FDA Announces Voluntary Recalls of Defendants' Contaminated Valsartan</u>

69. On or about July 13, 2018, the FDA announced that ZHP, Huahai US, Prinston, Solco, Teva, Actavis, Cardinal, Harvard, Major, Arrow, and Actavis Pharma were voluntarily

recalling their Valsartan products manufactured by ZHP.[2] The recall was for products distributed as early as October 2015. However, based upon investigation, it is likely that Defendants' Valsartan manufactured in November 2011 and beyond by ZHP was also contaminated with NDMA and NDEA.

70. Subsequently, the FDA announced numerous additional recalls of Valsartan and other similar products manufactured or distributed, and sold by both the ZHP and Aurobindo Defendants and non-parties.[3] The FDA has not released the results of its investigation into when Aurobindo started manufacturing Valsartan containing NDEA.

G. FDA's November 29, 2018 Warning Letter to ZHP

71. On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of its Chuannan facility.[4] The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

72. The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012.

73. ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." More specifically, ZHP "approved a [V]alsartan API process change . . . that included the use of the solvent [redacted]. [ZHP's] intention was to

[2] FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm (last accessed Apr. 5, 2019).
[3] FDA UPDATES ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Apr. 5, 2019).
[4] FDA, ZHEJIANG HUAHAI PHARMACEUTICAL 11/29/18, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628009.htm (last accessed Apr. 5, 2019).

improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities[, such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process."

74. The FDA added that ZHP "also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in [its] [V]alsartan API before [it] approved the process change. [ZHP is] responsible for developing and using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes."

75. ZHP claimed that it had followed "common industry practice." Importantly, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." The FDA "strongly" recommended that ZHP hire a cGMP consultant and referred ZHP to four guides on cGMPs.

76. On September 28, 2018, the FDA stopped allowing ZHP to deliver its drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that

the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

H. Defendants Knew that Their Valsartan Contained Unacceptably High Amounts of NDMA or NDEA, a Probable Human Carcinogen

77. The FDA has concluded that "NDMA and NDEA are probable human carcinogens and should not be present in drug products"[5] ZHP Defendants' Valsartan was reported to have tested for between 0.5 and 20 micrograms of NDMA.[6]

78. NDMA and NDEA are not FDA-approved ingredients for branded Diovan or generic Valsartan. Moreover, none of Defendants' Valsartan products (or any Valsartan product, for that matter) identifies NDMA or NDEA as an ingredient on the products' labels or elsewhere. This is because NDMA and NDEA are probable human carcinogens and are not approved to be included in Valsartan.

79. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the NDMA and NDEA contamination almost immediately.

80. 21 C.F.R. § 211.110 contains the cGMP's regarding the "[s]ampling 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.

[5] FDA UPDATES ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Apr. 5, 2019).
[6] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm (last accessed Apr. 5, 2019).

21 C.F.R. § 211.110(c). ZHP and Aurobindo violated this and numerous other applicable regulations and duties.

81. Defendants' own quality control units were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP or Aurobindo.

82. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the NDMA and NDEA contamination in Defendants' Valsartan products would have been discovered in or about November 2011. Defendants were thus on (at minimum) constructive notice that their Valsartan products were contaminated and adulterated as early as that date.

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

84. As set forth above, FDA investigators have observed ZHP deviating from cGMPs since at least March 2007. In May 2017, among the numerous violations found, 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. In the case of Aurobindo, the FDA found that Aurobindo was inadequately investigating deviations of its products as early as 2014. From 2016 to 2018, the FDA repeatedly observed that Aurobindo was violating cGMPs that would have protected the identity, strength, quality, and purity of its drug products.

85. These discoveries by the FDA's investigators suggest that Defendants were specifically aware of impurities in the drugs being manufactured by ZHP and Aurobindo, including specifically contamination of Defendants' Valsartan with NDMA or NDEA. The efforts to

manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce contaminated, adulterated Valsartan into the U.S. market.

86. Defendants were also specifically aware of ZHP's and Aurobindo's manufacturing issues based on Defendants' awareness of cGMP violations as early as March 2007 in the case of ZHP and sometime in 2014 for Aurobindo, based on their own monitoring of ZHP and Aurobindo and of the Valsartan products being manufactured at ZHP and Aurobindo, and based on the FDA's inspections of ZHP's and Aurobindo's facilities.

87. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA or NDEA. Defendants failed to recall their generic Valsartan products because they were motivated to maximize profits at the expense of safety and 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.

I. Defendants' Warranties and Deceptive Statements Regarding Their Generic Valsartan Products

88. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers, physicians, and others about their contaminated, adulterated Valsartan products.

89. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[7] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange

[7] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Apr. 5, 2019).

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.

90. 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.

91. 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 physicians and patients that their products are in fact the same as and are therapeutically interchangeable with Diovan, and are free of contamination with unapproved substances such as NDMA and NDEA.

92. On its January 29, 2019 website,[8] ZHP stated that it "has established an independent, strict and sound quality mangement [sic] system in accordance with GMP." ZHP further claims that it "ensure[s] that production is operated in accordance with GMP and product quality meets the required specifications," and that ZHP's "workshops of formulation are designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."

93. Huahai US assisted Prinston in acquiring approval of its ANDA for Valsartan.

94. Prinston lists its Valsartan as equivalent to Diovan on its website.[9]

[8] ZHP completely changed its website sometime in February or March 2019.
[9] Prinston, PRODUCT LIST, http://www.prinstonpharm.com/Products_List.html#v (last visited Apr. 5, 2019).

95. Furthermore, Solco states on the "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."[10]

96. On the "Drug Safety" page of its website, Solco states that "Solco Healthcare is committed in providing . . . its patients with high quality, FDA-approved generic medications."[11]

97. 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.[12]

98. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."[13]

99. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[14]

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[10] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last accessed Apr. 5, 2019).
[11] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Apr. 5, 2019).
[12] Solco, VALSARTAN TABLETS, http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last accessed Apr. 5, 2019).
[13] Teva, Company PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/ (last visited Apr. 5, 2019).
[14] *Id.*

100. In a March 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their Valsartan products were "bioequivalent" to Diovan.

101. Cardinal's Standards of Business Conduct state, "We have quality systems in place to ensure that we manufacture, handle, store and distribute products in accordance with applicable legal and regulatory requirements. Every employee is responsible for following our quality processes when working with the products we sell."[15] The Standards also require Cardinal to "[u]nderstand and comply with the policies that cover the manufacture, storage, handling and distribution of products we sell."[16]

102. Harvard also follows Cardinal's Standards.[17]

103. Harvard describes its Valsartan as Diovan on its website.[18]

104. Major's June 2018 Product Catalog compared its Valsartan to Diovan.[19]

105. Major "also maintain[s] strong relationships with generic manufacturers and suppliers who we routinely audit to ensure compliance with our standards."[20]

106. Major follows Cardinal's Standards of Business Conduct.[21]

107. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. **All of our manufacturing**

[15] Cardinal, STANDARDS OF BUSINESS CONDUCT, https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-standards-of-business-conduct-booklet-english.pdf (last visited Apr. 5, 2019).
[16] *Id.*
[17] Harvard, COMPLIANCE, https://www.theharvarddruggroup.com/compliance/ (last visited Apr. 5, 2019).
[18] Harvard, SEARCH RESULTS FOR VALSARTAN, https://www.theharvarddruggroup.com/shop/item/get-list/type/search?term=valsartan (last visited Apr. 5, 2019).
[19] Major removed Valsartan from its current catalog. *See* Major, FEBRUARY 2019 PRODUCT CATALOG, https://www.majorpharmaceuticals.com/wp-content/uploads/Product-Catalog.pdf (last visited Apr. 5, 2019).
[20] Major, MAJOR® RX SOLUTIONS, https://www.majorpharmaceuticals.com/rx-solutions/ (last visited Apr. 5, 2019).
[21] Major, COMPLIANCE, https://www.majorpharmaceuticals.com/compliance/ (last visited Apr. 5, 2019).

processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[22]

108. Teva USA's Code of Conduct affirms, "**To ensure we are in compliance and working in accordance with sound quality principles in** our research laboratories, in our clinical trials, and in **our manufacturing plants and distribution centers, we adhere to the systems and internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP).**"[23]

109. Teva USA maintains a Brand-to-Generic Medication Reference on its website.[24] Before its recall of Valsartan, this Reference included Valsartan products and their brand-name equivalents.

110. Torrent Pharmaceutical's website states, "At Torrent, we strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."[25]

111. Aurobindo's website states that it is "Committed to Quality and Safety."[26]

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[22] Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/ (last visited Apr. 5, 2019).
[23] Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/ (last visited Apr. 5, 2019).
[24] Teva USA. PATIENTS: RESOURCES, https://www.tevagenerics.com/patients/resources/ (last visited Apr. 5, 2019).
[25] Torrent Pharmaceuticals, MANUFACTURING, http://www.torrentpharma.com/Index.php/site/info/manufacturing (last visited Apr. 5, 2019).
[26] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited Apr. 5, 2019).

112. On January 6, 2015, Aurobindo announced that it had received FDA approval to manufacture and market Valsartan, adding that Valsartan is the "the generic equivalent to the reference listed drug product (RLD) Diovan®."

113. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[27] Aurobindo also "[s]eek[s] to attain the highest quality standards."[28]

114. Aurobindo USA's website lists Diovan as its Valsartan's "Brand Reference."[29]

115. Aurolife states, "The Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP compliant manufacturing facility with an investment of over US $50 million."[30]

116. 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 and implied warranties to consumers that the medication was a generic form of Diovan, and 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 contaminated or adulterated.

117. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their labels, websites, brochures, and other

[27] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last visited Apr. 5, 2019).
[28] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last visited Apr. 5, 2019).
[29] Aurobindo USA, VALSARTAN TABLETS, https://www.aurobindousa.com/product-category/valsartan-tablets/ (last visited Apr. 5, 2019).
[30] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last visited Apr. 5, 2019).

marketing or informational materials that their Valsartan product was the equivalent of Diovan, and that it complied with cGMPs, contained only the ingredients identified on the products' FDA-approved labels, and did not contain (or were not likely to be contaminated) any substance besides those identified on the products' FDA-approved labels.

118. The presence of NDMA or NDEA in Defendants' Valsartan (1) renders Defendants' Valsartan products contaminated and dangerous; (2) renders these contaminated 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; (3) was the result of intentional, negligent, and willful gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants' express warranties of sameness; and (4) results in Defendants' Valsartan containing an unapproved carcinogenic 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, specifically failing to disclose the contamination with NDMA or NDEA.

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

120. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, NDMA and NDEA are not FDA-approved ingredients in Valsartan. The presence of NDMA or NDEA in Defendants' Valsartan means that Defendants have violated express and implied warranties to Plaintiff and other Class Members. The presence of NDMA or

NDEA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for their ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' express warranties and implied warranty of merchantability and/or fitness for ordinary purposes.

121. For these and other reasons, Defendants' Valsartan is therefore contaminated and thus adulterated as 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).

122. No consumer would knowingly purchase a contaminated, adulterated Valsartan product or even be permitted to purchase contaminated, 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. Other alternate medical treatments and therapies were also available.

J. Fraudulent Concealment and Tolling

123. Plaintiff's and Class Members' causes of action accrued no earlier than the date the FDA announced the recall of Defendants' generic Valsartan products.

124. Alternatively, any statute of limitations 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 and Aurobindo's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NDMA and/or NDEA, and were not the same as brand Diovan.

125. For example, Defendants failed to reveal to the public that their Valsartan products contained NDMA or NDEA or was otherwise contaminated, adulterated, or non-therapeutically

equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection reports that preceded the recall announcements were heavily redacted (including the names of the drugs affected by ZHP's and Aurobindo's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

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

127. For instance, Huahai US publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[31]

128. Because of this, Plaintiff and other Class Members did not discover, nor would they discover through reasonable and ordinary diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' intentional concealment, false and misleading explanations, and obfuscations, lulled Plaintiff and other Class Members into believing that their Valsartan was the same as Diovan, with no dangerous contaminants, despite their exercise of reasonable and ordinary diligence.

129. 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 efforts, Plaintiff and other Class Members 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.

[31] Huahai, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, https://www.huahaius.com/media.html (last accessed Apr. 5, 2019).

K. Plaintiff's Individual Facts

130. Plaintiff is a resident of Passaic, New Jersey.

131. On or about multiple dates, including but not limited to July 11, 2017, September 26, 2017, October 29, 2017, and March 26, 2018, Plaintiff purchased and later consumed contaminated Valsartan manufactured, labeled, marketed, distributed, and/or sold by Defendants and bearing NDC Numbers 43547-0369-09 and 65862-572-90.

132. The contaminated Valsartan consumed by Plaintiff and manufactured, labeled, marketed, distributed, and/or sold by Defendants was not therapeutically equivalent to brand Diovan, and was not manufactured in compliance with cGMPs.

133. Defendants illegally sold contaminated, adulterated Valsartan to Plaintiff.

134. As a result of the consumption of NDMA and NDEA, Plaintiff has been physically harmed, including but not limited to suffering cellular and genetic injury which creates and/or increases the risk that Plaintiff will develop cancer.

135. Medical monitoring of Plaintiff's condition is necessary and required because of the nature of cancer, including the need for diagnosis and treatment as early as possible.

136. In the absence of medical monitoring to diagnose and treat cancer as early as possible, Plaintiff and other Class Members are at an increased risk of suffering from the development and progression of cancer, with delayed diagnosis significantly increasing the risk of harm and death.

L. Extraterritorial Application of New Jersey Law as to Defendants

137. As alleged above, the ZHP, Huahai US, Prinston, Solco, Actavis, Actavis Pharma, Torrent Pharma, Aurobindo, Aurobindo USA, and Aurolife (collectively,"NJ Defendants") maintain their corporate headquarters in New Jersey.

138. A substantial portion of the express and implied warranties and other wrongdoing subsequent to the contamination of the API in China and India alleged herein were made from and originated from NJ Defendants' respective headquarters in New Jersey.

139. A substantial portion of the aforesaid conduct, including but not limited to failure to test or properly assure quality control, misrepresentations and/or material omissions regarding the therapeutic equivalence of Defendants' Valsartan products to brand Diovan, and regarding Defendants' cGMP violations and/or distribution and marketing of adulterated Valsartan in the United States occurred and/or originated from NJ Defendants' New Jersey headquarters.

140. Plaintiff intends to seek additional discovery to show that Defendants' warranties and breach thereof, and other breaches of common law and wrongdoing occurred and emanated primarily from New Jersey.

V. CLASS ACTION ALLEGATIONS

141. Plaintiff brings this action both individually and as a class action pursuant to Federal Rule of Civil Procedure 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 consumed generic Valsartan contaminated with NDMA or NDEA, manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since November 2011, and suffered cellular and/or genetic injury, have developed cancer, and/or are at an increased risk of developing cancer as a result of exposure to the contamination, but have not yet been diagnosed with cancer.

142. In the alternative, Plaintiff alleges sub-classes for all individuals in each State, territory, or possession who consumed generic Valsartan contaminated with NDMA or NDEA, manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since November 2011, and suffered cellular and/or genetic injury, have

developed cancer, and/or are at an increased risk of developing cancer as a result of exposure to the contamination, but have not yet been diagnosed with cancer. Collectively, the foregoing Nationwide Class and alternative state sub-classes are referred to as the "Class."

143. 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.

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

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

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

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

a. Whether each Defendant's Valsartan product was contaminated with NDMA or NDEA;

b. Whether each Defendant's Valsartan product containing NDMA or NDEA was adulterated;

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

d. Whether Defendants negligently or defectively manufactured the Valsartan consumed by Plaintiff and other Class Members;

e. Whether Defendants misrepresented facts or failed to warn, as to the contamination;

f. Whether each Defendant made express or implied warranties of "sameness" to Plaintiff and other Class Members regarding their generic Valsartan products;

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

h. Whether each Defendant affirmatively misrepresented that its Valsartan product was the same as brand Diovan and thus therapeutically interchangeable, or omitted the fact that it was not;

i. Whether each Defendant affirmatively misrepresented that it was compliant with cGMPs, or omitted the fact that it was not;

j. Whether Plaintiff and other Class Members have been injured and/or are at increased risk of harm as a result of each Defendant's unlawful conduct, and the amount of damages;

k. The nature and extent of medical monitoring, testing, examinations, and treatment necessary to address the risks created by Plaintiff's and other Class Members' consumption of Valsartan contaminated with NDMA or NDEA;

l. Whether a common damages model can calculate damages on a class-wide basis;

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

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

148. **Typicality**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and other Class Members all suffered the same type of harm, including exposure to NDMA and/or

NDEA, cellular and/or genetic injury, cancer, and/or an increased risk of developing cancer, but have not yet been diagnosed with cancer. Plaintiff has substantially the same interest in this matter as all other Class Members, and her claims arise out of the same set of facts and conduct as all other Class Members.

149. **Adequacy of Representation**: Plaintiff is committed to pursuing this action and has retained competent counsel experienced in pharmaceutical and products liability litigation, consumer litigation, class actions, and federal court litigation. Accordingly, Plaintiff and her counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members she seeks to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

150. 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.

151. 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 plaintiffs. Plaintiff's counsel, highly experienced in pharmaceutical and product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

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

152. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

153. Each Defendant owed a duty to Plaintiff and other members of the Class to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its Valsartan products.

154. Each Defendant owed a duty to Plaintiff and the Class to ensure that the Valsartan products it sold in the United States were not contaminated with NDMA or NDEA, contained only the ingredients stated in the label, were therapeutically equivalent to brand Diovan, and/or complied with cGMPs, and/or was not contaminated or adulterated.

155. Each Defendant owed a duty of care to Plaintiff and the members of the Class because they were the foreseeable, reasonable, and probable users of Valsartan products. Each Defendant knew, or should have known, that its Valsartan product was contaminated with NDMA and/or NDEA, did not contain only the ingredients stated, 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.

156. Defendants negligently manufactured the Valsartan at issue, causing contamination with NDMA and NDEA, which are carcinogens.

157. Each Defendant failed to fulfill its duty of care. Each Defendant inadequately conducted or oversaw the manufacture, testing, labeling, distribution, marketing, warnings,

disclosures, and sale of the Valsartan at issue. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiff and other Class Members.

158. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiff and other Class Members, and the medical and regulatory communities, of the potential and actual contamination with NDMA and/or NDEA as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a carcinogen and thus causing continued exposure to the carcinogenic contamination, and delaying necessary testing, examinations, surveillance, and treatment.

159. Defendants' negligent conduct created and then exacerbated and worsened an unreasonable, dangerous condition for Plaintiff and other Class Members.

160. Defendants acted with recklessness and willful and wanton disregard for the health of Plaintiff and other Class Members.

161. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiff and other Class Members, and created a foreseeable risk of harm to Plaintiff and other Class Members.

162. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and other Class Members have suffered injury including cellular and genetic damage, causing cancer or increasing the risk of cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

163. WHEREFORE, Plaintiff demands judgment on her behalf and on behalf of all other Class Members, of injunctive and monetary relief, including the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to

NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, and (4) to provide for all necessary evaluations and treatment; compensatory damages, punitive damages, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

164. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

165. 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 equivalent to and interchangeable with brand Diovan. In other words, Defendants expressly warranted that their products were the same as Diovan.

166. Each Defendant sold Valsartan products that they expressly warranted were compliant with cGMP, and/or not contaminated or adulterated.

167. 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 contaminated or adulterated.

168. 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 express warranties: 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.

169. At the time that each Defendant marketed and sold their Valsartan products, 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 contaminated or adulterated.

170. Each Defendant breached its express warranties with respect to their Valsartan products as they were not the same as brand Diovan, not of merchantable quality, were not fit for their ordinary purposes, and did not comply with cGMP, and/or were contaminated or adulterated.

171. As a direct and proximate result of each Defendant's breach of express warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants'

Valsartan products they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

172. WHEREFORE, Plaintiff demands judgment on her behalf and on behalf of all other Class Members, of injunctive and monetary relief, including the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, and (4) to provide for all necessary evaluations and treatment; compensatory damages, punitive damages, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR ORDINARY PURPOSE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

173. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

174. 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.

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

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

177. Each Defendant was obligated to provide Plaintiff and other Class Members reasonably fit Valsartan products for the purpose for which the products were sold, and to conform to the standards of the trade in which Defendants are involved such that the products were not contaminated with a carcinogen and were of fit and merchantable quality.

178. 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.

179. Each Defendant breached its implied warranty because each Defendant's Valsartan product was contaminated with a carcinogen and not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

180. 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 products they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

181. WHEREFORE, Plaintiff demands judgment on her behalf and on behalf of all other Class Members, of injunctive and monetary relief, including the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, and (4) to provide for all necessary evaluations and treatment; compensatory damages, punitive damages, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION
MANUFACTURING DEFECT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

182. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

183. The Valsartan at issue was defectively manufactured, as the manufacturing process caused contamination of the Valsartan with NDMA and NDEA.

184. Valsartan contamination with NDMA and/or NDEA is by definition defectively manufactured.

185. Defendants' conduct in defectively manufacturing Valsartan was reckless and taken with wanton and willful disregard for the health of Plaintiff and other Class Members.

186. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured Valsartan.

187. As a direct and proximate result, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan products they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

188. WHEREFORE, Plaintiff demands judgment on her behalf and on behalf of all other Class Members, of injunctive and monetary relief, including the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, and (4) to provide for all necessary evaluations and treatment; compensatory damages, punitive damages, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just

FIFTH CAUSE OF ACTION
FAILURE TO WARN
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

189. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

190. Defendants failed to warn Plaintiff and the Class Members, and the medical and regulatory communities, of the potential or actual contamination of the Valsartan with NDMA and NDEA, as soon as this was suspected or known.

191. Defendants' failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiff and other Class Members, causing exposure to carcinogens and delay of diagnosis and treatment.

192. Defendants are strictly liable for their failure to warn or adequately disclose information.

193. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan products they consumed were contaminated with NDMA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

194. WHEREFORE, Plaintiff demands judgment on her behalf and on behalf of all other Class Members, of injunctive and monetary relief, including the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical

procedures for diagnosis and treatment, and (4) to provide for all necessary evaluations and treatment; compensatory damages, punitive damages, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff requests entry of Judgment providing for relief including:

A. Certifying this Action as a class action;

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

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

D. Awarding appropriate preliminary and/or final injunctive relief;

E. Directing the Defendants to fund medical monitoring in an amount sufficient to fund necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, and treatment, as necessary and appropriate;

F. Payment to Plaintiff and other Class Members of compensatory damages and punitive damages;

G. An award of attorneys' fees and costs;

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

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

JURY DEMAND

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

TRIAL ATTORNEY DESIGNATION

Plaintiff designates Adam M. Slater as trial attorney.

Dated: April 5, 2019

RESPECTFULLY SUBMITTED,

Adam M. Slater (NJ Bar 046211993)
MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway, 2nd Floor
Roseland, New Jersey 07068
Tel.: 973-228-9898
Fax: 973-228-0303
aslater@mazieslater.com

Counsel for Plaintiff and the Class

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby further certify to the best of my knowledge that many related cases have been filed in New Jersey and throughout the country, including the recently created MDL in which this action is filed.

Dated: April 5, 2019

RESPECTFULLY SUBMITTED,

Adam M. Slater (NJ Bar 046211993)
MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway, 2nd Floor
Roseland, New Jersey 07068
Tel.: 973-228-9898
Fax: 973-228-0303
aslater@mazieslater.com

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

Paulette Silberman, Individually and on behalf of all others similarly situated

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway, 2nd Floor, Roseland, New Jersey 07068
973-228-9898

DEFENDANTS

Zhejiang Huahai Pharmaceuticals Co., Ltd., et al.

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

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

Attorneys *(If Known)*
DUANE MORRIS LLP
30 South 17th Street, Philadelphia, Pennsylvania 19103
215-979-1175

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

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

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

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

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

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

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

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

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

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)*:
Class Action Fairness Act, 28 U.S.C. § 1332(d)

Brief description of cause:
Plaintiff needs medical monitoring after consuming Defendant's Valsartan contaminated with carcinogens.

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ In excess of $5,000,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Judge Robert B. Kugler DOCKET NUMBER 19-md-2875

DATE 04/05/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE