UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.: _____

MSP RECOVERY CLAIMS, SERIES LLC,
a Delaware entity,

Plaintiff,

v.

HUAHAI US INC.; PRINSTON PHARMACEUTICAL, INC.; SOLCO HEALTHCARE U.S., LLC; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD;

Defendants.
_____/

PLAINTIFF'S CLASS ACTION COMPLAINT FOR DAMAGES

MSP Recovery Claims, Series LLC ("MSPRC") brings this class action on behalf of similarly-situated healthcare insurers (the "Class Members") to recover payments unlawfully induced by Huahai US, Inc. ("Huahai US"); Prinston Pharmaceuticals, Inc. ("Prinston"); Solco Healthcare U.S., LLC ("Solco"); Teva Pharmaceuticals Industries, Ltd. ("Teva Industries"); Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, the "Valsartan Defendants"); and Zhejiang Huahai Pharmaceutical Co., Ltd ("ZHP").[1]

NATURE OF THE ACTION

1. When physicians prescribe, patients consume, and health insurance companies pay for a pharmaceutical drug, they have a right to expect that the drug has been manufactured

[1] Certain healthcare benefit providers have assigned their recovery rights to plaintiff MSPRC. MSPRC asserts those rights it has obtained through the assignments described more fully below.

with quality and care, *i.e.*, that the drug is safe and has the quality, purity, identity, and strength represented by its manufacturer. As a foundation of that trust, a manufacturer must comply with what are called current Good Manufacturing Practices ("cGMPs"). 21 U.S.C. § 351(a)(2)(B). If a drug is not manufactured in compliance with those standards, it is deemed adulterated, worthless, and prohibited from being distributed and sold in the United States. *Id*.

2. Since at least 2014, the Valsartan Defendants have manufactured or sold hundreds of millions of dollars in worthless, adulterated generic Valsartan—a widely-popular prescription drug mainly used to treat high blood pressure and congestive heart failure. To obtain maximum profits by minimizing costs, the Valsartan Defendants outsourced to a Chinese manufacturer—ZHP—production of the core active pharmaceutical ingredient ("API") that is used to synthesize Valsartan. The Valsartan Defendants outsourced that production despite knowing or having reason to know that ZHP's chronic and documented cGMP violations would result in the production of ingredients that are unfit and unsafe for human consumption. Today, because of ZHP's repeated violations of cGMPs, nearly half of all Valsartan drugs the Valsartan Defendants are currently selling in the United States are contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic—and liver-damaging—contaminant.[2]

3. This is no minor contamination. Nitrosamines such as NDMA are well-known to be carcinogenic and have been used widely in cancer research for that very reason. Anecdotally,

[2] ABC NEWS, *FDA Expands Recall of Common Heart Medication Valsartan*, available at https://abcnews.go.com/Health/fda-expands-recall-common-heart-medication-valsartan/story?id=57092400 (last accessed Dec. 14, 2018) ("Valsartan-containing drug products with active pharmaceutical ingredients supplied by [ZHP] make up nearly 43% percent of the U.S. market share of valsartan-containing drug products since January 2018.").

NDMA was the poison of choice in two sensational murders in the U.S. and Germany.[3] Because smoking cigarettes produces NDMA, smoking in public places has been banned. Animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."[4] Simply put, no doctor would prescribe, no patient would consume, and no insurance company would pay for, a drug that contained NDMA, a probable human carcinogen.

4. Following the shocking revelation that nearly half of the Valsartan currently being sold in the United States contained a probable human carcinogen, on July 13, 2018, the U.S. Food and Drug Administration ("FDA") announced a voluntary recall of all Valsartan products manufactured by ZHP. A list of all currently recalled Valsartan products can be found here https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf (the "Valsartan Drugs," which includes contaminated Valsartan already sold and paid for by Plaintiff's assignors and the Class Members).

5. On September 28, 2018, the FDA banned ZHP from further importing Valsartan API into the United States until it could determine the full extent of the NDMA contamination. European regulators for more than 20 European countries took similar steps. Although the investigation into the scope of the contamination is still underway, the FDA already has

[3] Chase Purdy, *A Common Blood-Pressure Medicine is Being Recalled Because of a Toxic Ingredient*, available at https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/ (last accessed Dec. 14, 2018).

[4] U.S. ENVIRONMENTAL PROTECTION AGENCY, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)*, available at https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf (last accessed Dec. 14, 2018).

announced the recall of another, related "sartan" drug called Losartan, also manufactured by ZHP, because it is contaminated with N-nitrosodiethylamine ("NDEA")—another nitrosamine carcinogen.[5]

6. The extensive contamination caused by ZHP cannot have come as a surprise to the Valsartan Defendants. As early as May 2017, the FDA criticized ZHP's production facilities for failing to comply with cGMPs. In one inspection, the FDA discovered that ZHP's Linhai City facility (where Valsartan was being manufactured) repeatedly was re-testing out-of-specification samples until it obtained a desirable result. ZHP also routinely dismissed questionable test results without providing any kind of scientific explanation, in violation of cGMPs. On information and belief, ZHP was manipulating its data to intentionally conceal that it was producing Valsartan contaminated with a known human carcinogen.

7. ZHP's cGMP violations began long before 2017. According to the FDA, ZHP's cGMPs violations began no later than 2012, when ZHP changed the manufacturing process it used to synthesize Valsartan. To increase efficiency and yield, ZHP replaced one chemical compound (tributyltin azide) with another, more toxic compound (sodium azide), which required use of sodium nitrite. This process, according to leading chemists, would inevitably produce nitrosamines (such as NDMA and NDEA) as a by-product, because it is widely known that use

[5] This class action focuses on the production and unlawful sale of Valsartan-containing contaminated Valsartan API produced by ZHP. It recently came to light that defendant Teva and another generic manufacturer, Mylan, N.V., have been selling Valsartan containing contaminated Valsartan API that was manufactured in India and contains NDEA. Teva's practice of outsourcing the production of Valsartan API to plants that do not follow cGMPs has resulted in Teva's recalling all of its Valsartan drugs from the U.S. market.

of nitrites causes formation of nitrosamines.[6]

8. Making matters worse, ZHP violated cGMPs by never testing whether this new process could safely produce uncontaminated Valsartan API. In fact, following the July 13th recall, the FDA found ZHP to be in further violation of cGMPs, because it had "fail[ed] to evaluate all potential risks from the . . . manufacturing process change."[7] According to the FDA's recent inspection, ZHP has been producing contaminated "valsartan-containing products for as long as four years."[8]

9. On November 29, 2018, the FDA issued a warning letter to ZHP, condemning ZHP for "fail[ing] to adequately assess the potential formation of mutagenic impurities when [it] implemented the new process . . . ."[9] The FDA also discovered that, in September of 2016, ZHP received complaints that it was producing contaminated Valsartan API. Instead of testing its process and fixing what was causing the impurity, ZHP shockingly "reprocessed and released [the contaminated drug] to customers in non-U.S. markets."[10] The FDA recently disclosed that its investigation had "uncovered serious manufacturing violations at ZHP . . . and these

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[6] ECA ACADEMY, *Valsartan: What Caused the Contamination?*, available at https://www.gmp-compliance.org/gmp-news/valsartan-what-caused-the-contamination (last accessed Dec. 14, 2018).

[7] U.S. FOOD AND DRUG ADMINISTRATION, *Form 483 Dated Aug. 3, 2018*, available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf (last accessed Dec. 14, 2018).

[8] *Id.*

[9] FDA, *Warning Letter: 320-19-04 dated Nov. 29, 2018*, available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628009.htm (last accessed Dec. 14, 2018).

[10] *Id.*

violations reveal a disturbing lack of oversight at this API manufacturer that puts patients at risk."[11]

10. Despite knowing at all material times how ZHP (their contract manufacturer) manufactured its Valsartan API, despite repeated warnings that ZHP was violating cGMPs, and despite complaints that ZHP was producing contaminated Valsartan API, the Valsartan Defendants did nothing to cause ZHP to correct its violations and ensure that the Valsartan API it manufactured satisfied cGMPs. Instead, the Valsartan Defendants continued to manufacture and distribute huge quantities of adulterated and dangerous Valsartan, fraudulently misrepresented its quality and safety, and collected hundreds of millions of dollars in unlawful payments annually from Plaintiff's assignors and Class Members.

11. In doing so, the Valsartan Defendants, knowingly and with an intent to defraud, concealed from Plaintiff and Class Members the material facts concerning ZHP's pervasive cGMP violations, and made express and implied representations to Plaintiff's assignors and Class Members that the Valsartan Drugs conformed to applicable standards of quality, purity, identity and strength, were not adulterated, and were merchantable, fit for human consumption and fit for their intended purpose when, in truth and in fact, the Valsartan Drugs were contaminated with a probable human carcinogen.

12. Each package of Valsartan Drugs sold in the United States contained a printed insert which represented that the drug in the package had the specified properties, conformed to the specified description, and carried a guarantee of quality assurance. The Valsartan Defendants

[11] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Warns API Manufacturer Involved in Valsartan Recall, Provides Information for Patients Taking These Medications*, Dec. 11, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628189.htm (last accessed Dec. 14, 2018).

knowingly or extremely recklessly made these representations with actual knowledge, or reason to know, that they were false, because the Valsartan Defendants had outsourced production to a Chinese company that was committing egregious cGMP violations and using a new production process that caused contamination.

13. The Valsartan Defendants' misrepresentations and omissions were material to the decisions by Plaintiff's assignors and Class Members to pay for the Valsartan Drugs, and in paying for those drugs, Plaintiff's assignors and Class Members reasonably relied on those misrepresentations and omissions. Plaintiff's assignors and the Class Members would not have continued paying for the drugs if they had known the drugs were adulterated, which meant the drugs could not lawfully be sold or distributed, and were, therefore, worthless. Plaintiff and the Class Members have the right to recover all sums of money they paid for the drugs.

14. Plaintiff's assignors and Class Members paid the majority of amounts charged by the Valsartan Defendants for the Valsartan Drugs and, consequently, were the direct and primary victims of Defendants' scheme to defraud. In the years since Valsartan went on sale as a generic, Plaintiff's assignors paid approximately $79 million for generic Valsartan containing Valsartan API manufactured by ZHP. Similarly situated Class Members paid tens of millions more. And although the Valsartan Defendants' scheme affected non-parties—*e.g.*, patients and doctors—Plaintiff's claims are not dependent on the conduct of others who also may have relied on and been deceived by the Valsartan Defendants' misrepresentations and omissions. Defendants' scheme could not have achieved its objective—to realize massive profits from the sale of drugs that were falsely represented to be merchantable, fit for human consumption and their intended purpose, but were in fact adulterated, dangerous and worthless—without the continuing, annual payment of hundreds of millions of dollars by Plaintiff's assignors and Class Members.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331.

16. Under 28 U.S.C. § 1391 and 18 U.S.C. § 1965, venue is proper in the United States District Court for the Southern District of Florida because the claims alleged in this action accrued in this district and defendants regularly transact their affairs in this district.

17. This Court has personal jurisdiction over each of the defendants because the defendants conduct business in Florida, maintain and carry on continuous and systematic contacts with Florida and this judicial district, regularly transact business within Florida and this judicial district, and regularly avail themselves of the benefits of their presence in Florida and this judicial district.

THE PARTIES

18. Plaintiff MSPRC is a Delaware series limited liability company with its principal place of business at 5000 S.W. 75th Avenue, Suite 400, Miami, Florida 33155. MSPRC's limited liability company agreement provides for the establishment of one or more specific Series. All records of all Series are maintained together with all assets of MSPRC.

19. Certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to Series LLCs of MSPRC. Pursuant to MSPRC's limited liability agreement, all rights arising from the assignment to its series (including the assignments discussed below), along with the right to bring any lawsuit in connection with that assignment (including those below), belong to MSPRC. As such, MSPRC has the right and power to sue defendants to recover the payments at issue in this action.

20. Defendant Huahai US is a New Jersey corporation and maintains its principal

place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Huahai US is a subsidiary of ZHP. At all times material to this action, Huahai US has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district.

21. Defendant Prinston is a Delaware corporation and maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. At all times material to this action, Prinston has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district.

22. Defendant Solco is a Delaware limited liability company and maintains its principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512. At all times material to this case, Solco has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district. Solco is a fully owned subsidiary of Prinston and ZHP.

23. Defendant Teva Industries is a foreign company incorporated and headquartered in Peta Tikvah, Israel. Teva, on its own and through subsidiaries, regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this action, Teva has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district.

24. Defendant Teva USA, a Delaware corporation, is a wholly owned subsidiary of Teva Industries, and maintains its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. At all times material to this action, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district.

25. Defendant ZHP is a foreign corporation organized and existing under the laws of the People's Republic of China, and maintains its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. At all times material to this action, ZHP has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan throughout the United States, including Florida and this district.

26. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

1. Valsartan Background

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

28. Valsartan is the generic version of the registered listed drug ("RLD") Diovan® ("Diovan"), which was marketed in tablet form by Novartis AG ("Novartis") beginning in July 2001. Diovan was an immensely popular drug, generating $2.33 billion in sales in the United States until its patents expired in 2012.

29. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. NDMA also is not an FDA-approved ingredient of any generic Valsartan product.

30. Although Novartis's Diovan patents expired in September 2012, Diovan was not immediately subject to generic competition because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to obtain FDA approval for its generic Valsartan until approximately June 2014, which delayed other generic competition (under the Hatch-Waxman

Act) until Ranbaxy achieved FDA approval and began to market its generic drug.

2. The Generic Drug Approval Framework

31. Under the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355, *et seq.*, branded drug companies are required to submit a New Drug Application ("NDA") and demonstrate clinical safety and efficacy through well-designed clinical trials.

32. In contrast, generic drug companies such as the Valsartan Defendants submit what is called an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the branded drug or the RLD. Bioequivalence is defined as the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

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

34. Because the right to sell generic drugs is based on bioequivalence, generic drug manufacturers have an ongoing duty under federal law to ensure the bioequivalence of their products with the RLD. At all times, federal law requires a generic manufacturer to show, among other things, that: the active ingredients are the same as the RLD, 21 U.S.C. § 355(j)(2)(A)(ii); and the generic drug is "bioequivalent" to the RLD and "can be expected to have the same

therapeutic effect," *id.* at (A)(iv). Like a brand manufacturer, a generic manufacturer also must make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see* 21 U.S.C. § 355(b)(1)(C). Finally, a generic manufacturer also must 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).

35. When the FDA approves a generic drug, it states that 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 reasonably expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant this interchangeability through the inclusion of the same labeling as the RLD in each and every prescription of their generic drug.

36. The FDA has approved fifteen (15) ANDAs for generic Diovan, *i.e.*, Valsartan.

3. The FDA's Enforcement of cGMPs

37. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers, *inter alia*, the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*

38. The FDA endeavors to ensure the safety and efficacy of drugs taken by millions of Americans through a combination of approvals, inspections and enforcement, but also relies on drug manufacturers to self-regulate and act responsibly in the public interest. In the FDA's view, drug manufacturers have "a virtual fiduciary relationship to the public." Eric M. Blumberg, *Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug and Cosmetic Act*, 55 FOOD & DRUG L.J. 148 (2000).

39. In fulfillment of its statutory duties, the FDA enforces cGMPs, which impose on pharmaceutical companies minimum requirements for manufacturing, processing, packaging, and holding drugs, to assure they meet safety, quality, purity, identity and strength standards. *See* 21 U.S.C. § 351.

40. Federal regulations, set forth in 21 C.F.R. Parts 210 and 211, provide 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 extraterritorial jurisdiction to enforce these regulations if a facility is making drugs intended to be distributed in the United States.

41. The FDA has emphasized that cGMP compliance is critical in assuring that drugs are safe, effective, and fit for their intended use.

42. Any drug that fails to satisfy applicable cGMPs is deemed to be "adulterated" and may not be directly or indirectly introduced or delivered for introduction into interstate commerce or distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Sections 351(a)(2)(A) and (B) provide that a drug "shall be deemed adulterated":

> [I]f it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or . . . if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

43. Under 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).

44. Indeed, FDA regulations require a "quality control unit" to independently test drug productions manufactured by another company on contract, such as was the case here, where ZHP served as a contract manufacturer for the Valsartan Defendants. Specifically:

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

21 C.F.R. § 211.22(a).

4. ZHP's Chronic cGMP Violations

45. The Valsartan Defendants outsourced the production of Valsartan API to ZHP, which has API manufacturing facilities located in Linhai City, Zhejiang Province, China. ZHP was one of the first Chinese companies approved by the FDA to manufacture and sell generic drugs in the United States and is one of China's largest exporters of pharmaceuticals to the United States and the European Union.[12]

46. Because ZHP served as contract manufacturer of the defendants' Valsartan Drugs, the Valsartan Defendants had a quality assurance obligation under federal law, as set forth above, with respect to ZHP's processes and finished products.

47. On information and belief, ZHP changed its Valsartan manufacturing process in

[12] ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., *About Us*, available at http://en.huahaipharm.com/content.asp?info_kind=001002 (last accessed Dec. 14, 2018).

or about 2012. Before the process change, in order to synthesize the tetrazole cycle in the Valsartan molecule, ZHP used a compound called tributylin azide. To increase yield, ZHP replaced tributylin azide with sodium azide. However, because sodium azide is highly toxic, the process required use of sodium nitrate to "destroy" excess sodium azide in the finished product. At all times relevant to this action, it was well-known that under acidic conditions (such as those involved in synthesizing Valsartan), sodium nitrate forms nitrous acid, which can react with another solvent in the synthesis process (dimethylamine) to generate nitrosamines, such as NDMA and NDEA. After ZHP changed its manufacturing process it never tested whether that process could produce uncontaminated Valsartan on a commercial scale.

48. Moreover, despite the Valsartan Defendants' duty under 21 C.F.R. § 211.22(a) to ensure that contract manufacturers comply with cGMPs, at no time did they investigate whether ZHP's changed process could produce uncontaminated Valsartan on a commercial scale. On the contrary, ZHP and the Valsartan Defendants knew or had reason to know that the Valsartan produced by the new process would be contaminated with nitrosamines, such as NDMA or NDEA. In fact, a recent FDA investigation revealed that on September 13, 2016, ZHP received a complaint that its API tested higher than the acceptable range for a known carcinogen. *See* n.9 *supra*.

49. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A). The U.S. Environmental Protection Agency also classified NDMA as a probable human carcinogen by giving it a "B2" rating, which means that is "probably carcinogenic to humans." WHO, *Guidelines for Drinking-Water Quality*, available at https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf (last

accessed Dec. 14, 2018).

50. Accordingly, NDMA is not an FDA-approved ingredient for Diovan or generic Valsartan. None of defendants' Valsartan Drugs (or any Valsartan product, for that matter) identifies NDMA as an ingredient on product labels or anywhere else.

51. ZHP's cGMP violations go beyond having produced Valsartan API on a commercial scale since 2012 without verifying whether its changed processes would result in adulterated Valsartan API contaminated with a human carcinogen and poison. In fact, as early as 2007, the FDA had found that ZHP was violating cGMPs for other reasons.

52. The FDA inspected ZHP's Linhai City facilities from March 27 through March 30, 2007, and found numerous cGMP violations.[13] ZHP purported to later correct those violations. However, on September 13, 2016, ZHP received a complaint that its API contained more than the acceptable range of a known carcinogen.[14] ZHP's investigation of the contamination failed to evaluate other API batches to determine whether there was "an adverse trend."[15] In fact, several other batches also tested out of specification for the carcinogen but were not mentioned in ZHP's investigation. Rather, ZHP reprocessed and redistributed the contaminated API to its customers in non-U.S. markets.[16] Through such egregious conduct, as further demonstrated below, ZHP and the Valsartan Defendants placed its own profits over

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[13] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Letter to Minghua Zhou*, available at http://online.wsj.com/public/resources/documents/huahai3-10092007.pdf (last accessed Dec. 14, 2018).

[14] *See* n.9, *supra*.

[15] *Id.*

[16] *Id.*

consumer safety. The FDA condemned ZHP's violations as "reveal[ing] a disturbing lack of oversight . . . that puts patients at risk."[17]

53. Moreover, from May 15, 2017 through May 19, 2017, the FDA again inspected ZHP's Linhai City facilities. In that inspection, the FDA found that ZHP repeatedly had re-tested out of specification ("OOS") samples until obtaining a desirable result.[18] The FDA found that ZHP had begun this practice no later than September 2016. The May 2017 inspection resulted in an FDA finding that "impurities occurring during analytical testing are not consistently documented/quantitated."[19]

54. According to the FDA's 2017 report, ZHP routinely had invalidated OOS sampling results without conducting any kind of scientific investigation of the reasons for the OOS sampling. In fact, in one documented instance, the OOS result was attributed to "pollution" in the environment surrounding the facility. These are indicia of systematic data manipulation intended to intentionally conceal and recklessly disregard the presence of toxic impurities such as NDMA.

55. The inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility.[20] The FDA

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[17] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Warns API Manufacturer Involved in Valsartan Recall, Provides Information for Patients Taking These Medications*, Dec. 11, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628189.htm (last accessed Dec. 14, 2018).

[18] U.S. FOOD AND DRUG ADMINISTRATION, *Form 483 dated May 19, 2017*, available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM616397.pdf (last visited Dec. 14, 2018).

[19] *Id.*

[20] *See id.*

found equipment that was rusting, and that 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 found in batches of Valsartan API.[21]

56. The FDA ordered a recall of defendants' Valsartan on July 13, 2017. Following that recall, the FDA issued another report of an inspection conducted from July 23 to August 3.[22] In that report, the FDA found that ZHP had violated cGMPs by "release[ing] API manufactured from crude intermediaries with OOS levels of genotoxic impurities without conducting a thorough investigation."[23] In other words, even though ZHP knew its Valsartan API was contaminated, it did nothing to find out why and simply kept producing it.

5. Defendants' Fraudulent and Deceptive Statements About the Valsartan Drugs

57. Each Valsartan Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions about their adulterated Valsartan Drugs, to Plaintiff and Class Members.

58. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[24] The Orange Book is a public document, and the Valsartan Defendants sought and received a listing of their Valsartan

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[21] *See id.*

[22] U.S. FOOD AND DRUG ADMINISTRATION, *Form 483 dated Aug. 3, 2018*, available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf (last accessed Dec. 14, 2018)

[23] *Id.*

[24] U.S. FOOD AND DRUG ADMINISTRATION, *Approved Drug Products with Therapeutic Equivalence Evaluations*, available at https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Dec. 14, 2018).

Drugs in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, the Valsartan Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to branded Diovan.

59. Maintaining therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. The FDA's Orange Book states that therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.[25]

60. By introducing their Valsartan Drugs into the United States market under the name "Valsartan" (a) as a therapeutic equivalent to branded Diovan and (b) with an FDA-approved label that is the same as the label for Diovan, the Valsartan Defendants represented and warranted to end users that their products were the same as, and interchangeable with, branded Diovan.

61. Furthermore, Defendant Solco states on its "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication." SOLCO HEALTHCARE U.S., *About Solco*, available at http://www.solcohealthcare.com/about-solco.html (last accessed Dec. 14, 2018).

62. On the "Drug Safety" page of Solco's website, Solco states that "Solco Healthcare is committed in providing . . . its patients with high quality, FDA-approved generic medications." SOLCO HEALTHCARE U.S., *Drug Safety*, available at http://www.solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Dec.

[25] U.S. FOOD AND DRUG ADMINISTRATION, *Orange Book Preface*, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm (last accessed Dec. 14, 2018).

14, 2018).

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

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

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

TEVA PHARMACEUTICAL INDUSTRIES, LTD., *Generics FAQs*, available at https://www.tevapharm.com/our_products/generic_qa/ (last accessed Dec. 14, 2018).

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

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

Id.

66. Similarly, on its webpage entitled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" through Teva's "impeccable adherence to … [cGMPs][.]" TEVA PHARMACEUTICALS INDUSTRIES, LTD., *Uncompromising Quality*, available at https://www.tevapharm.com/about/profile/quality_assurance/ (last accessed Dec. 14, 2018).

67. Defendant Prinston states on its website that "[w]e deliver and maintain high

quality and integrity in all of our products, which are manufactured in world-class cGMP (current Good Manufacturing Practices) manufacturing facilities." PRINSTON PHARMACEUTICALS, *About Us*, available at http://www.prinstonpharm.com/about_us.html (last visited Dec. 14, 2018).

68. In addition to these representations, each package of the Valsartan Defendants' Valsartan Drugs contained an FDA-approved label. By using an FDA-approved label, the Valsartan Defendants made representations to consumers and healthcare insurers (including Plaintiff's assignors and the Class Members), as well as express and implied warranties, of the "sameness" of their Valsartan Drugs to Diovan. They also represented and warranted that their Valsartan Drugs were not adulterated, and possessed the safety, quality, purity, identity, and strength characteristics reflected in their FDA-approved labels.

69. In addition, on information and belief, the Valsartan Defendants affirmatively misrepresented and warranted to consumers and healthcare insurers—through their websites, brochures, and other marketing or informational materials—that their Valsartan Drugs complied with cGMPs and did not contain any ingredients other than those identified on the Valsartan Drugs' FDA-approved labels.

70. If the Valsartan Defendants had not routinely disregarded the FDA's cGMPs and instead had properly discharged their non-delegable, quality-assurance duties, they would have discovered the NDMA contamination promptly after it occurred, instead of leaving it to be discovered five (5) years later.

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

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

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

21 C.F.R. § 211.110(c).

72. Under this provision, the Valsartan Defendants' own quality control units were responsible for testing, and approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

73. If the Valsartan Defendants had complied with these sampling and quality-control cGMPs, the NDMA contamination in the Valsartan Drugs promptly would have been discovered in 2012, when ZHP changed its processes to lower manufacturing and wholesales costs. At a minimum, ZHP's shenanigans gave the Valsartan Defendants reason to know, and put them on constructive notice, that their Valsartan Drugs were adulterated, because ZHP had adopted a manufacturing process likely to cause nitrosamine contamination.

74. ZHP, Huahai US, Solco, and Prinston are owned by their corporate parent, Huahai Pharmaceutical. Accordingly, Huahai US, Solco, and Prinston had actual or imputed knowledge of ZHP's intentional or reckless breach of applicable cGMPs and its attempts to manipulate its sampling data and conceal the NDMA contamination.

75. The Valsartan Defendants' breach of their non-delegable duty to comply with sampling-related and quality-control-related cGMPs caused the Valsartan Drugs to be adulterated. 21 U.S.C. § 351(a)(2)(B). Thus, the distribution and sale of the adulterated Valsartan Drugs was unlawful, 21 U.S.C. § 331, rendering false the Valsartan Defendants' express representations that the drugs were manufactured in compliance with federal law and could lawfully be distributed and sold.

THE REPRESENTATIVE ASSIGNMENT AGREEMENTS

76. Certain series of MSPRC have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assignors' health plan members and enrollees. These assignments authorize the series and, in turn MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. For example, and only to serve to further demonstrate standing, MSPRC alleges a few of the assignments below as examples.

77. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC. Specifically, the assignments, attached as **Composite Exhibit A**, state the following:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

Comp. Ex. A, at 2, 4.

78. On May 12, 2017, Summacare, Inc. ("Summacare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC ("MSP Recovery"). Specifically, the assignment, attached as **Exhibit B**, provides the following

language:

> [Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

Ex. B, at 1-2.

79. On June 12, 2017, MSP Recovery irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of Plaintiff:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery] . . . .

Exhibit C, at 1. Summarcare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery to Series 16-11-509, which is memorialized in a letter dated September 5, 2018, and attached as **Exhibit D**

80. On March 20, 2018, Connecticare, Inc. ("Connecticare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC. Specifically, the assignment, attached as **Exhibit E**, provides the following language:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may

> have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

Ex. E, at 2.

PLAINTIFF'S ASSIGNORS
PAID FOR CONTAMINATED VALSARTAN

81. Since at least 2014, defendants have manufactured and distributed Valsartan Drugs throughout the United States, for which Plaintiff's assignors paid $79 million on behalf of their enrollees. On information and belief, Plaintiff's assignors' payments include those payments for defendants' contaminated Valsartan Drugs, which were also manufactured, distributed, and sold during that same period.

82. For example, and only to further demonstrate standing, MSPRC alleges some exemplar payments made by its assignors for the Valsartan Drugs in the table below. In each instance, one of MSPRC's assignors received a request to cover a prescription drug on behalf of an enrollee for a particular date of service indicated below. The assignors accepted coverage for these requests and paid the amounts indicated for contaminated, FDA-recalled lots of Valsartan Drugs. To be clear, the table below does not demonstrate all of MSPRC's assignors' payments for contaminated Valsartan Drugs, let alone all of MSPRC's damages.[26]

Assignor	Assignor's Enrollee[27]	Date of Service	Amount Paid
Emblem	T.A.	12/18/2017	$ 195.19

[26] The representative payments in the table below correspond to the FDA's list of recalled Valsartan Drugs with expiration dates ranging from 2018 through 2020. The table below does not list any payments made for Valsartan Drugs whose contamination was not disclosed prior to the FDA's recall.

[27] To ensure that this complaint complies with federal law under the Health Insurance Portability and Accountability Act ("HIPAA"), the individual enrollees are referred to by their initials.

Emblem	E.M.	7/21/2017	$ 193.30
Emblem	E.L.	9/11/2017	$ 192.02
Emblem	G.S.	6/19/2017	$ 174.63
Emblem	R.M.	9/11/2017	$ 170.94
Summacare	B.R.	10/10/2016	$ 89.93
Summacare	S.Z.	12/13/2016	$ 503.89
Summacare	S.F.	3/31/2017	$ 39.60
Summacare	J.S.	5/30/2017	$ 69.12
Summacare	J.S.	11/14/2016	$ 239.14
Connecticare	R.P.	8/24/2017	$ 103.45
Connecticare	W.J.	10/15/2017	$ 75.20
Connecticare	A.W.	8/3/2017	$ 71.15
Connecticare	E.S.	9/21/2017	$ 69.45
Connecticare	S.G.	3/9/2017	$ 52.34

CLASS REPRESENTATION ALLEGATIONS

83. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiff brings this class action on its own behalf and on behalf of all Class Members nationwide. Plaintiff seeks class certification of the claims alleged in this action and judgment for damages against the Valsartan Defendants for itself and on behalf of the Class.

84. The Class is defined as follows, and consists of:

Nationwide Class as to Counts I-IV, VI, and VII

All third-party payers and consumers who paid for NDMA-contaminated Valsartan (the "Class"). Excluded from the Class are: the Valsartan Defendants; any parent,

subsidiary, or affiliate of any Defendants; any entity in which any of the Valsartan Defendants have or had a controlling interest, or which any of the Valsartan Defendants otherwise controls or controlled; and any officer, directors, employee, legal representative, predecessor, successor, or assign of any of the Valsartan Defendants.

Florida Subclass as to Count V – Florida Deceptive and Unfair Trade Practices Act

All third-party payers and consumers who paid for NDMA-contaminated Valsartan (the "Class"). Excluded from the Class are: the Valsartan Defendants; any parent, subsidiary, or affiliate of any Defendants; any entity in which any of the Valsartan Defendants have or had a controlling interest, or which any of the Valsartan Defendants otherwise controls or controlled; and any officer, directors, employee, legal representative, predecessor, successor, or assign of any of the Valsartan Defendants.

A. Federal Rule of Civil Procedure 23(a)

85. Federal Rule of Civil Procedure 23(a) provides for class certification where the representative plaintiff demonstrates that:

1. the class is so numerous that joinder of all members is impracticable;

2. there are questions of law or fact common to the class;

3. the claims or defenses of the representative parties are typical of the claims or defenses of the class; and

4. the representative parties will fairly and adequately protect the interests of the class.

(1) Numerosity

86. On information and belief, the Class includes hundreds of third-party payers, as well as hundreds of thousands of consumers throughout the United States, such that individual joinder of each Class member is impracticable.

(2) Commonality

87. Plaintiff and the Class Members assert claims that raise common questions of law

and fact.

88. Some of the common questions of law and fact include:

(a) Whether the Valsartan Defendants manufactured and distributed contaminated Valsartan in violation of cGMPs;

(b) Whether the Valsartan Defendants knew or had reason to know that they were manufacturing and selling contaminated Valsartan in violation of cGMPs;

(c) Whether the Valsartan Defendants engaged in fraudulent and deceptive conduct by manufacturing and selling contaminated Valsartan;

(d) Whether the Valsartan Defendants engaged in a pattern and practice of selling contaminated Valsartan;

(e) Whether the Valsartan Defendants and ZHP constitute an enterprise within the meaning of 18 U.S.C. § 1961(4);

(f) Whether the Valsartan Defendants and ZHP have committed acts of mail and wire fraud;

(g) Whether the Valsartan Defendants and ZHP have engaged in a pattern of racketeering activity;

(h) Whether the Valsartan Defendants have used or invested income from their racketeering activities to establish an enterprise in violation of 18 U.S.C. § 1962(a);

(i) Whether the Valsartan Defendants have conducted or participated in the affairs of an enterprise through a pattern of racketeering in violation of 18 U.S.C. § 1962(c);

(j) Whether the Valsartan Defendants have been unjustly enriched;

(k) Whether the Valsartan Defendants breached express and implied warranties;

(l) Whether the Valsartan Defendants violated FDUPTA and state consumer protection statutes;

89. The common questions identified above predominate over questions, if any, that may affect only individual Class Members.

90. The Valsartan Defendants subjected Plaintiff and the Class Members to the same harm and did so in the same manner.

(3) Typicality

91. Plaintiff's claims are typical of the claims of Class Members because they are based on the same legal theory, arise from the similarity, uniformity, and common purpose of defendants' unlawful conduct, and are not subject to any unique defenses. Members of the Class have sustained damages in the same manner as Plaintiff, as a result of defendants' wrongful conduct.

92. Plaintiff's claims are typical because the Valsartan Defendants, through their misrepresentations and omissions, caused Plaintiffs and the Class Members to pay for adulterated and contaminated Valsartan for which Plaintiff and the Class never should have had to pay. Plaintiff's claims also are typical because the Valsartan Defendants deceived Plaintiff and the Class Members in exactly the same way, through knowing, reckless or negligent misrepresentations, as well as express and implied warranties, that the Valsartan Drugs were in compliance with cGMPs, and were merchantable and fit for their intended purpose when, in fact, they were not.

(4) Adequacy of Representation

93. Plaintiff and its attorneys will fairly and adequately protect and represent the interests of the Class. Plaintiff is a member of the Class defined above, is committed to the active

and vigorous prosecution of this action, and has retained competent counsel experienced in litigation of this nature.

94. There is no hostility of interests between Plaintiff and the Class and there will be no difficulty in the management of this litigation as a class action.

B. Federal Rule of Civil Procedure 23(b)

95. Questions of fact or law common to Plaintiff's and the Class Members' claims predominate over any questions of law or fact affecting only individual Class Members. All claims by Plaintiff and Class Members arise from the Valsartan Defendants' common course of unlawful conduct. The predominating questions of law and fact include those set forth above in Paragraph 88.

96. Common issues predominate where, as here, liability can be determined on a class-wide basis, even if there might be the need for some individualized damages determinations. As a result, in determining whether common questions predominate, courts focus on the liability issue, and if the liability issue is common to the class, as it is in this case, common questions will be held to predominate over individual questions.

97. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because a class action is the most manageable and efficient way to resolve the individual claims of each Class Member.

98. Specifically, a class action is the superior method of adjudicating Plaintiff's and the Class Members' claims because it will provide Class Members with what may be their only economically viable remedy. Moreover, there are no known Class Members who are interested in individually controlling the prosecution of separate actions. In addition, a class action will concentrate all litigation in one forum, which will conserve judicial and party resources with no

unusual manageability problems, because issues regarding the Valsartan Defendants' liability and the nature of Class Members' damages will be determined by class-wide proof, while the amounts of Class Members' damages will be determined by class-wide methods of data processing and computation.

CAUSES OF ACTION

COUNT I
Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964
(Against all defendants)

99. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

100. Plaintiff asserts a cause of action under 18 U.S.C. § 1964(c) on behalf of itself and all similarly-situated healthcare insurers.

101. The defendants violated 18 U.S.C. § 1962(c) by participating in or conducting the affairs of the Valsartan Enterprise (as described more fully below) through a pattern of racketeering activity.

102. Plaintiff and the Class Members are "persons" within the meaning of 18 U.S.C. § 1961(3), and each is a "person injured in his or her business or property" by reason of the defendants' violation of RICO within the meaning of 18 U.S.C. § 1964(c).

A. The Valsartan Enterprise

103. The Valsartan Defendants and ZHP are "persons" within the meaning of 18 U.S.C. 1961(3).

104. These persons, and others presently unknown, have been members of and constitute an "association-in-fact enterprise" within the meaning of 18 U.S.C. § 1962(c), and will be referred to herein collectively as the Valsartan Enterprise.

105. The Valsartan Enterprise, which engaged in and whose activities affected,

interstate and foreign commerce, is an association-in-fact of individuals and corporate entities within the meaning of 18 U.S.C. § 1961(4), and consists of "persons" associated together for a common purpose.

106. The purpose of that Valsartan Enterprise was to maximize their profits and sell as much of the Valsartan Drugs as possible, by disregarding whether those drugs complied with cGMPs.

107. The Valsartan Enterprise had an ongoing organization with an ascertainable structure and functioned as a continuing unit with separate roles and responsibilities.

108. Further, the Valsartan Enterprise had an existence that was separate and distinct from the pattern of racketeering in which ZHP and the Valsartan Defendants engaged. The Valsartan Defendants contracted with ZHP to produce various APIs for use in various pharmaceutical drugs that complied with cGMPs, and were lawfully sold in the United States.

109. ZHP and the Valsartan Defendants participated in the conduct, direction and control of the Valsartan Enterprise, but have an existence separate and distinct from the Valsartan Enterprise.

110. The Valsartan Enterprise provided defendants with the means to maximize their profits from the sale of Valsartan Drugs by disregarding whether those drugs complied with the applicable cGMPs. To achieve this goal, the Valsartan Defendants outsourced production of the Valsartan API to ZHP—a manufacturer they knew or had reason to know was producing Valsartan API on a commercial scale without verifying whether the process it was using would result in uncontaminated API. Moreover, the Valsartan Defendants outsourced production to ZHP despite knowledge of ZHP's numerous cGMP violations. As confirmed by the FDA's most recent investigation, ZHP's own records demonstrate that it has been producing contaminated

Valsartan API since at least 2014. *See* n.7, *supra*.

111. At all relevant times, ZHP and the Valsartan Defendants operated, controlled or managed the Valsartan Enterprise through a variety of actions. First, the Valsartan Defendants contracted with ZHP to produce the contaminated Valsartan API. Next, ZHP produced contaminated Valsartan API that did not comply with cGMPs. The Valsartan Defendants then received this contaminated Valsartan API and distributed it into the marketplace for sale.

112. ZHP and the Valsartan Defendants' participation in the Valsartan Enterprise was necessary for the successful operation of its scheme. The members of the Valsartan Enterprise shared and furthered a common purpose: to sell as much of the Valsartan Drugs as possible, and thereby maximize the revenue and profitability of the Valsartan Enterprise and its members. This common purpose is evidenced by ZHP's alteration of the Valsartan API manufacturing process in 2012, which contaminated the Valsartan API with NDMA, in an effort to produce more API annually at a lower cost. The members of the Valsartan Enterprise shared the bounty generated by the enterprise, *i.e*., by sharing the benefit derived from increased sales revenue generated by the scheme to defraud. Each member of the Valsartan Enterprise benefited from the common purpose: ZHP and the Valsartan Defendants sold more Valsartan API and Valsartan Drugs than they would have if the truth about the contamination had been known to Plaintiffs and Class Members.

B. The Predicate Acts

113. Section 1961(1) of RICO provides that "racketeering activity" includes any act indictable under 18 U.S.C. § 1341 (relating to mail fraud) and 18 U.S.C. § 1343 (relating to wire fraud). As set forth below, since at least 2014, the Valsartan Defendants and the members of the Valsartan Enterprise have committed numerous acts of mail and wire fraud in furtherance of

their unlawful scheme.

114. Each time the Valsartan Defendants manufactured and sold one of the Valsartan Drugs, they committed predicate acts of mail and wire fraud by misrepresenting that the drugs complied with applicable cGMPs. Similarly, each time ZHP manufactured and sold Valsartan API, it committed predicate acts of mail and wire fraud by misrepresenting that it had complied with applicable cGMPs. ZHP and the Valsartan Defendants made these misrepresentations extremely recklessly or with actual knowledge of falsity, because they knew or had reason to know their representations were false. Having made these misrepresentations many thousands of times over the course of several years, each member of the Valsartan Enterprise committed more than two predicate acts of mail and wire fraud.

115. Each of the defendants knew or had reason to know that these representations were false because ZHP—the outsourced contract manufacturer—was employing a process to produce Valsartan API that all defendants knew would result in contaminated Valsartan API. Moreover, all defendants knew that the FDA repeatedly had criticized ZHP for failing to comply with cGMPs. Despite knowledge of these facts, the Valsartan Defendants further violated cGMPs by failing to assess whether their contract manufacturer's processes complied with cGMPs and could produce uncontaminated Valsartan API on a commercial scale. Instead, the Valsartan Defendants knowingly or extremely recklessly sold massive quantities of contaminated Valsartan, while knowingly or extremely recklessly misrepresenting that their Valsartan Drugs were safe, conformed to cGMPs, and were lawful to distribute and sell in the United States.

116. Plaintiff and Class Members paid many millions of dollars for contaminated, unlawfully sold Valsartan Drugs, which could not have been sold but for the Valsartan Enterprise's fraudulent misrepresentations that the drugs were bioequivalent to Diovan, were

merchantable and fit for their ordinary use, and were manufactured and distributed in accordance with applicable laws and regulations, including cGMPs.

117. Healthcare insurers were primary targets and victims of defendants' unlawful scheme because they were the principal payers for the contaminated Valsartan Drugs. Defendants, acting through the Valsartan Enterprise, caused healthcare insurers (including Plaintiff's assignors and Class Members) to include the Valsartan Drugs in their "formularies," lists of drugs covered by health insurers' policies, through repeated, fraudulent misrepresentations that the drugs were bioequivalent to Diovan, were merchantable and fit for their ordinary use, and were manufactured and distributed in accordance with applicable laws and regulations, including cGMPs. The Valsartan Enterprise members' fraudulent misrepresentations were material to the decisions by Plaintiff's assignors and Class Members to include the Valsartan Drugs in their formularies. If Plaintiff's assignors and Class Members had known the Valsartan Drugs were adulterated and contaminated with NDMA, they would not have included the Valsartan Drugs on their formularies and would not have made any payments for those drugs.

118. In furtherance of the Valsartan Enterprise's fraudulent scheme, the defendants used the United States mail and interstate wires. For example, ZHP used these means in connection with selling Valsartan API that all defendants knew or had reason to know was contaminated. The Valsartan Defendants used these means to send and receive thousands (if not millions) of packages, advertisements, invoices, payments and other communications regarding the Valsartan Drugs. Each defendant conducted or participated, directly or indirectly, in the conduct of the Valsartan Enterprise's affairs through a pattern of unlawful activity within the meaning of 18 U.S.C. § 1961(5).

119. By reason of defendants' and the Valsartan Enterprise's predicate acts and pattern of racketeering activity, Plaintiff and the Class Members have been injured in their business or property by having paid (either completely or partially) for adulterated and contaminated Valsartan Drugs.

120. Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to Plaintiff and Class Members, who have the right to bring this action for three times their actual damages, as well as appropriate equitable relief, together with their costs and reasonable attorneys' fees in accordance with 18 U.S.C. § 1964(c).

121. Until the FDA banned the import of ZHP's Valsartan API on September 28, 2018, the defendants continuously engaged in these unlawful, predicate acts causing harm to the Class Members on a daily basis since at least 2012, which demonstrates a long-term racketeering activity and evidences the continuity of the Valsartan Enterprise's closed-ended pattern of racketeering activity.

COUNT II
Breach of Express Warranty
(Against the Valsartan Defendants)

122. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

123. The Valsartan Defendants expressly represented and warranted that their Valsartan Drugs could lawfully be sold in accordance with their ANDAs and FDA approvals, which required complying with applicable cGMPs. By putting their Valsartan Drugs into the stream of commerce, they also expressly warranted that their Valsartan Drugs were FDA-approved generic valsartan drugs that were bioequivalent to, and therefore therapeutically equal to and interchangeable with, Diovan. Thus, the Valsartan Defendants expressly warranted that their Valsartan Drugs could lawfully be sold and were the same as Diovan.

124. The Valsartan Defendants sold the Valsartan Drugs, which they expressly represented and warranted were compliant with cGMPs and not adulterated or contaminated.

125. The Valsartan Drugs did not conform to the Valsartan Defendants' express representations and warranties, because the drugs could not lawfully be sold, were not manufactured in compliance with cGMPs, and were adulterated and contaminated.

126. At all times when the Valsartan Defendants marketed and sold the Valsartan Drugs, they knew the purposes for which the drugs would be used, and expressly warranted that the products were the same as Diovan, complied with cGMPs, and not adulterated or contaminated. These representations and warranties became part of the basis of the bargain in Plaintiff's assignors' and Class Members' decisions to include the Valsartan Defendants' Valsartan Drugs in their formularies.

127. The Valsartan Defendants breached their express warranties with respect to their Valsartan Drugs because the drugs did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to Diovan, and could not lawfully be sold.

128. The Valsartan Defendants' breach of their express warranties were the direct and proximate cause of the Plaintiff's and Class Member's damages.

129. Plaintiff's damages include their assignors' payments for defendants' Valsartan Drugs that did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to Diovan, and could not lawfully be sold.

COUNT III
Breach of Implied Warranties of Merchantability and Fitness,
(Against the Valsartan Defendants)

130. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

131. Defendants all are "merchants" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

132. The Valsartan Drugs are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

133. The defendants were obligated to provide Plaintiff and the other Class Members reasonably fit Valsartan Drugs that were of merchantable quality, were reasonably fit for the purpose for which they were sold and conformed to the standards of the trade in which defendants are involved, such that their Valsartan Drugs were of fit and merchantable quality.

134. The defendants knew, had reason to know, and should have known that their Valsartan Drugs were being manufactured and sold for the intended purpose of human consumption as a safe alternative to, and the bioequivalent of, Diovan, and impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

135. The defendants breached their implied warranties, because their Valsartan Drugs were not of merchantable quality, nor fit for their ordinary purpose, and did not conform to applicable cGMPs.

136. Defendant's breaches of implied warranties were a direct and proximate cause of Plaintiff's and the Class Members' damages.

137. Plaintiff's damages include their assignors' payments for defendants' Valsartan Drugs, which were not of merchantable quality, were not fit for their ordinary purpose, did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to Diovan, could not lawfully be sold, and were so unmerchantable and unfit for their ordinary use as to have zero market value.

COUNT IV
Fraud / Negligent Misrepresentation
(Against all defendants)

138. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

139. Defendants made or caused to be made false and fraudulent representations of material facts, and failed to disclose material facts, to Plaintiff's assignors and all Class Members, with regard to defendants' Valsartan Drugs.

140. Defendants affirmatively misrepresented material facts, including the material misrepresentations that their Valsartan Drugs were therapeutically equivalent and bioequivalent to Diovan, that those drugs complied with cGMPs, could lawfully be sold, and were not adulterated or contaminated.

141. Defendants failed to disclose the material facts that their Valsartan Drugs were not therapeutically equivalent and bioequivalent to Diovan, did not comply with cGMPs, could not lawfully be sold, and were adulterated or contaminated.

142. Defendants' misrepresentations fraudulently induced Plaintiffs' assignors and Class Members to include the defendants' Valsartan Drugs in their formularies, which were used as the basis for causing them to pay for the Valsartan Drugs. Defendants knew, had reason to know, or should have known that the Valsartan Drugs were not therapeutically equivalent and bioequivalent to Diovan, that the drugs did not comply with GMPs, could not lawfully be sold, and were adulterated or contaminated. Plaintiff's assignors and the Class Members would not have paid any amounts of money for Defendants' Valsartan Drugs if they had known the truth.

143. Defendants knew, recklessly disregarded, or should have known, that their misrepresentations were materially false or misleading, or that their failure to disclose material facts rendered their representations false or misleading.

144. Defendants also knew, recklessly disregarded, or should have known, that their material misrepresentations and omissions would induce Plaintiff's assignors and the Class Members to pay some or all of the cost of defendants' Valsartan Drugs.

145. Defendants' misrepresentations and omissions were material.

146. Defendants made their misrepresentations and omissions with the intent to induce Plaintiff's assignors and the Class Members to pay for defendants' Valsartan Drugs.

147. But for Defendants' misrepresentations and omissions, Plaintiff's assignors and the Class Members would not have paid for defendants' Valsartan Drugs.

148. Plaintiff's assignors and the Class Members reasonably relied on defendants' material misrepresentations and omissions. Defendants' identical or substantially identical misrepresentations and omissions were communicated to Plaintiff's assignors and each Class Member through product labeling, marketing materials, and other public statements by defendants. But-for defendants' unlawful conduct, neither Plaintiff's assignors nor the Class Members would have included defendants' Valsartan Drugs in their formulary, nor paid any amount of money for the Valsartan Drugs.

149. Plaintiff and the Class Members have been damaged by defendants' misrepresentations and omissions as alleged herein.

COUNT V
Violations of Florida's Deceptive and Unfair Trade Practices Act, §§ 501.204, *et seq.*, Fla. Stat., and other UDAP Statutes
(Against all defendants)

150. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

151. Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), codified at sections 501.204, *et seq.*, Fla. Stat., prohibits "unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . ." § 501.204(1), Fla. Stat.

152. Plaintiff is a consumer within the meaning of section 501.203(7).

153. Under FDUTPA, "trade or commerce" is defined as "the advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated." § 501.203(8), Fla. Stat.

154. Defendants were and are engaged in "trade or commerce," in which they manufacturer, distribute, and sell prescription drugs or API.

155. Defendants made false and fraudulent misrepresentations that their Valsartan Drugs and the valsartan API were compliant with cGMPs, were bioequivalent to Diovan and could lawfully be sold. Defendants' failure to comply with cGMPs rendered the Valsartan Drugs adulterated or contaminated, and, accordingly, the distribution and sale of those drugs was and is unlawful. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

156. Defendants' deceptive and unfair practices were a direct and proximate cause of Plaintiff's and Class Members' damages.

157. Plaintiff's and the Class Members' damages include, but are not limited to, all payments made for the Valsartan Drugs.

158. Defendants benefited from their deceptive and unfair practices by unlawfully receiving payment for adulterated, contaminated Valsartan Drugs, which could not lawfully be distributed or sold in the U.S.

159. Under FDUTPA, Plaintiff is entitled to recover twice its actual damages, together with its attorneys' fees and costs. §§ 501.2105, 501.211, Fla Stat.

160. Non-Florida Class Members have a right to recover their damages for Defendants' unlawful conduct under the Unfair and Deceptive Acts and Practices ("UDAP")

statutes applicable to the claims of non-Florida Class Members.

COUNT VI
Unjust Enrichment
(Against all defendants)

161. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

162. Plaintiff's assignors and Class Members conferred a benefit on defendants by promptly paying for the Valsartan Drugs they purchased.

163. At all material times, the defendants were aware of the benefit conferred by Plaintiff's assignors and the Class Members.

164. Defendants knowingly and voluntarily accepted payments from Plaintiff's assignors and the Class Members for adulterated, contaminated Valsartan Drugs, which the Valsartan Defendants fraudulently represented as therapeutically equivalent and bioequivalent to Diovan, but did not comply with GMPs, could not lawfully be sold, and were adulterated or contaminated.

165. It would be unjust and inequitable for the Valsartan Defendants to retain the monies that Plaintiff's assignors and the Class Members paid for the worthless Valsartan Drugs.

166. Principles of law and equity require that the Valsartan Defendants disgorge the monies paid for the worthless Valsartan Drugs by Plaintiff's assignors and Class Members, and make restitution of those amounts to Plaintiff and Class Members.

COUNT VII
Disgorgement and Restitution of the Proceeds of Illegal Contracts
(Against the Valsartan Defendants)

167. Plaintiff incorporates by reference paragraphs 1 to 98 of this Complaint.

168. The Valsartan Defendants sold the Valsartan Drugs to Plaintiff's assignors and Class Members.

169. The Valsartan Drugs could not lawfully be sold, because they were not manufactured in compliance with cGMPs, and were adulterated or contaminated.

170. The Valsartan Defendants knew or had reason to know that the Valsartan Drugs could not lawfully be sold, because those drugs were not manufactured in compliance with cGMPs, and were adulterated or contaminated.

171. Every purchase agreement by which Plaintiff's assignors and the Class Members purchased and paid for the Valsartan Drugs was an illegal contract.

172. Plaintiff's assignors and the Class Members were unaware that the Valsartan Drugs could not lawfully be sold.

173. Because Plaintiff's assignors and the Class Members were innocent of the unlawful conduct that resulted in their paying for the Valsartan Drugs pursuant to illegal contracts, they have the right to recover the monies they paid to the wrongdoing Valsartan Defendants, and those defendants are required to disgorge those monies and make restitution in accordance with principles of equity and substantial justice.

JURY TRIAL DEMAND

174. Plaintiff demands a trial by jury on all of the issues raised in this complaint.

PRAYER FOR RELIEF

175. WHEREFORE, Plaintiff, individually and on behalf of the Class Members; pray for the following relief:

a. a finding that this action satisfies the prerequisites for maintenance of a class action under Federal Rule of Civil Procedure 23(a) and (b)(3), and certify the Class;

b. designation of Plaintiff as representative for the Class and Plaintiff's undersigned counsel as Class Counsel for the Class; and

c. a judgment against defendants that:

i. grants Plaintiff and the Class Members treble damages for those moneys the Class is entitled to under 18 U.S.C. § 1964(c);

ii. grants Plaintiff and the Class Members damages for those moneys the Class is entitled to under their direct right of recovery for breach of express and implied warranties, common law fraud, violations of FDUTPA, unjust enrichment, and restitution, and

iii. grants Plaintiff and the Class Members such other and further relief as the Court deems just and proper under the circumstances.

Dated: December 14, 2018.

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CERTIFICATE OF SERVICE

I certify that on December 14, 2018, I electronically filed this document with the Clerk of the Court using CM/ECF. I also certify that this document is being served today on all counsel of record either by transmission of Notices of Electronic Filing generated by CM/ECF or by U.S. Mail.

/s/ Andrés Rivero
ANDRÉS RIVERO