UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.: _____

MSP RECOVERY CLAIMS, SERIES LLC,
a Delaware entity,

Plaintiff,

v.

AUROBINDO PHARMA, LTD.; AUROBINDO USA, INC.; AUROLIFE PHARMA, LLC; HERITAGE PHARMACEUTICALS, LLC; EMCURE PHARMACEUTICALS; and JOHN DOES 1-100;

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 Aurobindo Pharma, Ltd.; Aurobindo USA, Inc.; Aurolife Pharma, LLC; Heritage Pharmaceuticals, LLC; Emcure Pharmaceuticals; and John Does 1-100 (collectively, the "Defendants") that Plaintiff and Class Members made for the Defendants' contaminated and adulterated Metformin drugs.[1]

NATURE OF THE ACTION

1. Metformin is the most prescribed oral pharmaceutical drug for patients with type 2 diabetes, especially overweight patients. Since its introduction in the United States in 1995,

[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.

Metformin has been the first-line treatment of type 2 diabetes. A brief review of the U.S. Food and Drug Administration's ("FDA") Drug Database reveals that metformin is sold by numerous pharmaceutical companies under various brands, including Glucophage, Fortamet, Glumetza, and Riomet, ("MCDs") and in generic form.[2] As of 2019, Metformin is the fourth most prescribed drug in the United States with more than 81 million prescriptions.[3] In fact, there are "no alternative medications that treat [type 2 diabetes] in the same way" as Metformin.[4]

2. In light of the volume of pharmaceutical drugs prescribed every day, is it critical to ensure that these drugs, including metformin, are safe to consume. Recent developments have questioned the safety of the pharmaceutical drug supply in the United States.

3. In July 2018, the FDA announced a recall of valsartan, a common medication used to treat high blood pressure in patients, because it was contaminated with N-nitrosodimethylamine ("NDMA"), a carcinogenic—and liver-damaging—contaminant. At the time, the valsartan recall, which also includes a recall of contaminated losartan, and irbesartan, was the largest recall of generic pharmaceuticals in U.S. history. While the FDA's investigation into the valsartan contamination is still pending, public information suggests that the Chinese and Indian manufacturers responsible for making the valsartan API modified their valsartan manufacturing processes, which caused every batch of valsartan API to become contaminated with NDMA.

4. On the heels of the valsartan recall, Valisure, an online pharmacy, sent the FDA a

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[2] Available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

[3] Available at https://clincalc.com/DrugStats/Top300Drugs.aspx.

[4] Available at https://www.fda.gov/news-events/press-announcements/statement-janet-woodcock-md-director-fdas-center-drug-evaluation-and-research-impurities-found.

Citizen Petition in September 2019, warning of the inherent dangers of ranitidine (or Zantac), an antacid that was prescribed more than 15 million times in 2016. Valisure's tests of ranitidine revealed that the drug contained more than 26,000 times the amount of NDMA that could safely be ingested.[5] The manufacturers of Zantac and generic ranitidine voluntarily recalled all the drugs, both over-the-counter and prescription.

5. In response to these events, the FDA announced that it would test all drugs in the United States to ensure that they were safe and not contaminated with cancer-causing NDMA.[6] On December 4, 2019, the Health Sciences Authority of Singapore ("HSA") had discovered that some types Metformin drugs were contaminated with NDMA. The HSA recalled two types entirely, Meijumet Prolonged Release Tablets in 750 mg and 1000 mg form manufactured by Pharmazen Medicals Pte Ltd., and recalled one batch of Glucient XR manufactured by Glorious Dexa Singapore.[7] News of the recall spread across the world, with various health regulators, including the FDA, announcing their own investigations into their local metformin.[8] In the U.S., the FDA announced that it was "investigating whether metformin in the U.S. market contains NDMA" by "work[ing] with companies to test samples of metformin sold in the U.S."[9]

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[5] Valisure Citizen Petition to FDA (Mar. 3, 2020), available at https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Metformin-v3.9.pdf (the "CP") (last accessed Apr. 3, 2020).

[6] Available at https://www.fda.gov/news-events/press-announcements/statement-janet-woodcock-md-director-fdas-center-drug-evaluation-and-research-impurities-found.

[7] Available at https://www.hsa.gov.sg/announcements/news/hsa-recalls-three-out-of-46-metformin-medicines.

[8] Available at https://www.raps.org/news-and-articles/news-articles/2019/12/metformin-regulators-respond-after-singapore-hsa?feed=Regulatory-Focus%3Futm_source%3DFacebook&utm_medium=social&utm_campaign=Regulatory-Focus.

[9] Available at https://www.fda.gov/news-events/press-announcements/statement-janet-woodcock-md-director-fdas-center-drug-evaluation-and-research-impurities-found.

6. On March 2, 2020, Valisure notified the FDA about the results of its own independent testing of Metformin. Using the testing methods similarly followed by the FDA, Valisure's tests revealed that the Metformin produced by Aurobindo and Heritage were contaminated with NDMA with levels between 37 and 266 ng per tablet. As to Heritage's Metformin products, the NDMA present was up to 8.6 times the FDA's interim daily limit.

7. 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, NDMA was the poison of choice in two sensational murders in the U.S. and Germany.[10] 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."[11] 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.

8. The Defendants knowingly and with an intent to defraud, concealed from Plaintiff and Class Members the material facts concerning their pervasive cGMP violations, and made express and implied representations to Plaintiff's assignors and Class Members that their Metformin drugs conformed to applicable standards of quality, purity, identity and strength, were

[10] 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 Apr. 3, 2020).

[11] 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 Apr. 3, 2020).

not adulterated, and were merchantable, fit for human consumption and fit for their intended purpose when, in truth and in fact, the Metformin drugs were contaminated with a probable human carcinogen.

9. Each package of Metformin 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 Defendants knowingly or extremely recklessly made these representations with actual knowledge, or reason to know, that they were false.

10. The Defendants' misrepresentations and omissions were material to the decisions by Plaintiff's assignors and Class Members to pay for the Metformin 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.

11. Plaintiff's assignors and Class Members paid the majority of amounts charged by the Defendants for the Metformin drugs and, consequently, were the direct and primary victims of Defendants' scheme to defraud. Since 2012, Plaintiff's assignors paid approximately $124 million for generic Metformin, which includes purchases made for Metformin contaminated with NDMA. Similarly situated Class Members paid millions more. And although the Defendants' scheme affected non-parties—for example, 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 Defendants' misrepresentations and omissions. Defendants' scheme could not have achieved its

objective—that is, 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

12. This Court has original jurisdiction pursuant to the Class Action Fairness Act ("CAFA"), 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.

13. Venue is proper in the United States District Court for the Southern District of Florida under 28 U.S.C. § 1391, because the claims alleged in this action accrued in this district and Defendants regularly transact their affairs in this district.

14. 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

15. 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 establishes one or more specific Series. All records of all Series are

maintained together with all assets of MSPRC.

16. Certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to Series LLCs of MSPRC. Under 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.

17. Defendant Aurobindo Pharma, Ltd. ("Aurobindo Pharma"), 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 or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in manufacturing, selling, and distributing adulterated or misbranded (or both) MCDs in the United States.

18. Defendant Aurobindo Pharma USA, Inc. ("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 Pharma. At all times material to this case, Aurobindo USA has been engaged in manufacturing, selling, and distributing MCDs in the United States.

19. Defendant Aurolife Pharma, LLC ("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, Aurolife has been engaged in manufacturing, selling, and distributing MCDs in the United

States.

20. Aurobindo, Aurobindo USA, and Aurolife are collectively referred to as the Aurobindo Defendants or "Aurobindo" in this Complaint.

21. Defendant Heritage Pharmaceuticals, Inc. ("Heritage Pharmaceuticals"), is a Delaware corporation with its principal place of business 12 Christopher Way #300, Eatontown, NJ 07724. At all times material to this case, Heritage Pharmaceuticals has been engaged in the manufacturing, sale, or distribution of MCDs in the United States. On information and belief, Heritage Pharmaceuticals is a subsidiary of India-based Defendant Emcure Pharmaceuticals.

22. Defendants Emcure Pharmaceuticals ("Emcure") is a foreign corporation with its principal place of business in Pune, India. Emcure on its own or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Emcure has been engaged in manufacturing, selling, and distributing adulterated or misbranded (or both) MCDs in the United States. On information and belief, Emcure is responsible for manufacturing MCDs sold by or through Heritage Pharmaceuticals in the United States. Upon information and belief, Heritage Pharmaceuticals is only involved in selling and marketing Emcure's MCDs in the United States. These two entities, together, will be referred to as "Heritage."

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

FACTUAL ALLEGATIONS

1. Metformin Background

24. Metformin is an oral diabetes medication that controls blood sugar levels without

increasing insulin.[12]

25. Metformin is an oral antihyperglycemic drug used as a first-line therapy in the treatment and management of type 2 diabetes. It is often referred to as the "gold standard" of diabetes management because it is well-tolerated and cost-effective.

26. Metformin was first discovered in 1922, and first marketed in the United States in 1995. Metformin is so critical to diabetes management that it is listed by the WHO on the WHO's List of Essential Medicines.

27. Metformin is the generic version of the registered listed drug ("RLD") Glucophage, which was marketed in tablet form by Bristol-Myers Squibb Company ("Bristol-Myers") beginning in March 1995. Glucophage was an immensely popular drug, generating $1.3 billion in sales in the United States in 1999.[13]

28. In 2019, Metformin was the fourth-most prescribed medicine in the United States, with more than 81 million prescriptions dispensed.

29. FDA-approved labels for branded MCDs specify their active and inactive ingredients. NDMA is not an FDA-approved ingredient of any branded MCD. NDMA also is not an FDA-approved ingredient of any generic Metformin product.

2. The Generic Drug Approval Framework

30. 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

[12] Available at https://www.drugs.com/metformin.html.

[13] Available at https://www.pharmaceuticalonline.com/doc/analysis-from-datamonitor-the-rise-and-fall-o-0002.

trials.

31. In contrast, generic drug companies such as the Defendants submit 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).

32. 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.

33. 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).

34. 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.

35. The FDA has approved more than twenty ANDAs for Metformin.

3. The FDA's Enforcement of cGMPs

36. 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, among other things, the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*.

37. 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).

38. 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.

39. 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.

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

41. 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.

42. 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).

43. Indeed, FDA regulations require a "quality control unit" to independently test drug productions manufactured by another company on contract. 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. The Valisure Citizen Petition

44. Valisure is an online pharmacy licensed in thirty-eight states and also an analytical laboratory accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and FDA (FEI #: 3012063246). Valisure has also maintained voluntary registration status with the FDA.

45. Valisure states that "its mission is to help ensure the safety, quality and consistency of medications and supplements in the market."

46. On March 2, 2020, Valisure submitted a Citizen Petition (the "CP") to the FDA regarding its findings of high levels of contamination of various generic metformin products with an IARC- and EPA-listed probable human carcinogen known as NDMA.

47. Valisure's CP states that "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule[.]"

48. Specifically with regard to generic Metformin products manufactured by Aurobindo and Heritage, Valisure's testing revealed NDMA contamination levels of between 37 and 266 ng/tablet, with levels reaching up to 8.6x the FDA's interim daily limit in Heritage's Metformin products.

5. Background on NDMA

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

50. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of 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 Apr. 3, 2020).

51. Accordingly, NDMA is not an FDA-approved ingredient for Glycophage or generic Metformin. None of Defendants' Metformin drugs (or any Metformin product, for that matter) identifies NDMA as an ingredient on product labels or anywhere else.

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

53. 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).

54. Accordingly, Defendants' own quality control units are and were responsible for

approving or rejecting drug products manufactured, processed, packed, or held under contract by Defendants.

55. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the NDMA contamination in Defendants' Metformin products would have been discovered almost as soon as the contamination commenced. Defendants were thus on (at minimum) constructive notice that their Metformin products were adulterated from that point forward.

6. Aurobindo's Chronic cGMP Failures

56. As noted in the Valisure CP, "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing." Aurobindo and its related subsidiaries and affiliates have been the subject of extensive FDA investigations revealing its seriously flawed and unreliable manufacturing practices and a history of recurring and ongoing cGMP violations.

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

58. Aurobindo manufactures MCDs 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 under federal law.

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

60. After an inspection of a Hyderabad facility from June 27 to July 1, 2016, the FDA told Aurobindo that its "[i]investigations 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."

61. 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." Fourth, the "use of instruments and recording devices not meeting establishes specifications was observed."

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

63. 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."

64. 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."

65. In February 2018, the FDA made nine more disturbing observations at Aurobindo's Hyderabad facilities. First, "[a]septic 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." Ninth, "[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."

66. It is clear Aurobindo has made no efforts at correct any of the previously identified errors, and continues to engage in grossly inadequate manufacturing processes. During an inspection in May 2019, an investigator made note of a panoply of serious issues which continue to call the integrity of the API manufacturing operations into question.

67. For example, in determining that the Medchal, Telangaga facility was not following quality control measures, and likewise did not have quality control procedures in place, the investigator observed "loose handwritten notebooks with what appears to be laboratory test data results."

68. While Aurobindo claimed to have performed tests and quality control activities on API as a result of the FDA's investigation into adulterated products, during the inspection, the investigator found that the API was not being adequately retained or appropriately identified, calling Aurobindo's testing of this API into question. More troubling, the API sampled and analyzed by the investigator was to set to be shipped into the United States.

69. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as 'incomplete data.'" The testing systems

also allowed certain employees to "verify incomplete data in raw data file." The investigator found that the quality control reviewers attested to practices which "contradict actual review practices performed by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data, other than the assorted loose notebooks found lying around the facility.

70. The investigator also noted that in addition to all of the gross processing and data integrity issues, *even the building itself* did not have the "suitable construction to facility cleaning, maintenance and proper operations." The investigator noted that in a stability sample storage room, they observed a "PVC pipe connected to an air conditioner unit on one end, and paced in a blue plastic bucket on the other end with approximate 50% of the bucket filled with condensate water." There were four other similar setups in other critical rooms in the facility.

71. Aurobindo is responsible for developing its manufacturing processes, maintaining appropriate controls and standard operating procedures, and implementing suitable analytical methods to detect and prevent potential impurities like NDMA. Instead of protecting against the potential formation of mutagenic impurities in its metformin manufacturing processes, Aurobindo's repeated violations of cGMPs and utter lack of disregard for quality control and assurance measures encouraged the proliferation of NDMA and did not provide the proper assurances that Aurobindo's MCDs met the requirements of the Food and Drug Cosmetics Safety Act and has the identity and strength, or met the quality and purity characteristics, which Aurobindo's MCDs purported to represent. As a result, Aurobindo willfully and recklessly introduced contaminated, adulterated and/or misbranded metformin containing products into the U.S. market.

7. Heritage's cGMP Failures

72. Heritage likewise has quality assurance obligations with respect to its processes and finished products as set forth above under federal law.

73. On information and belief, Heritage has repeatedly violated and ignored such obligations and quality assurance standards.

74. With respect to Heritage's manufacturing practices, Defendant Emcure has been investigated by the FDA at least 31 times since 2005.

75. The most recent inspection of Emcure's Indian manufacturing facility in February 2019 resulted in the strongest rebuke available to the FDA—a warning letter.

76. The FDA's August 2, 2019 warning letter cited Emcare for a variety of serious cGMP compliance issues, including incidents where a variety of microbacterial growths occurred in stability testing samples.

77. The FDA also found this was not the first time Emcure had been cited for their grossly inadequate manufacturing practices and stated that "failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate."

78. In a December 2018 inspection, the FDA also found that Emcure failed to establish the accuracy of their analytical methods needed to assess the raw materials used in the manufacture of API.

79. Systemically, the FDA also found that Emcure lacked any appropriate Quality Assurance and Quality Control measures to qualify or approve the supplier for critical raw materials, and intermediates used in manufacturing API.

80. With respect to Heritage Pharmaceuticals, the US-based marketing and distributing subsidiary of Emcure, in May of 2015 the FDA issued a Warning Letter noting multiple violations and failure to report post-marketing adverse drug experiences, questioning

Heritage's "ability to monitor the safety of drug products" and the "reliability and integrity" of its information and record keeping.

81. Heritage's failures to meet industry quality assurance standards have resulted in multiple voluntary recalls for "lack of sterility" relating to its finished drug products. For example, in May of 2019 Heritage recalled multiple lots of losartan manufactured in India due to detection of a known process impurity and contaminant above acceptable exposure limits.

82. Heritage is responsible for developing its manufacturing processes, maintaining appropriate controls and standard operating procedures, and implementing suitable analytical methods to detect and prevent potential impurities like NDMA. Instead of protecting against the potential formation of mutagenic impurities in its metformin manufacturing processes, Heritage's utter lack of disregard for quality control and assurance measures encouraged the proliferation of NDMA and did not provide the proper assurances that Heritage's MCDs met the requirements of the Food and Drug Cosmetics Safety Act and have the identity and strength, or met the quality and purity characteristics, which Heritage's MCDs purported to represent. As a result, Heritage willfully and recklessly introduced contaminated, adulterated or misbranded metformin containing products into the U.S. market.

8. Defendants' Fraudulent and Deceptive Statements About the Metformin Drugs

83. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions about their adulterated Metforin drugs to Plaintiff and Class Members.

84. The FDA maintains a list of "Approved Drug Products with Therapeutic

Equivalence Evaluations" commonly referred to as the Orange Book.[14] The Orange Book is a public document, and the Defendants sought and received a listing of their Metformin drugs in the Orange Book upon approval of their Metformin ANDAs. In securing FDA approval to market generic Metformin in the United States as an Orange Book-listed therapeutic equivalent MCDs, the Defendants were required to demonstrate that their generic Metformin products were bioequivalent to branded MCDs.

85. 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.[15]

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

87. In addition, each Defendant's Metformin product is accompanied by an FDA-approved label or medication guide (that is, a patient leaflet or patient information). By presenting consumers and third-party payers with FDA-approved Metformin labels or

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[14] 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 Apr. 3, 2020).

[15] U.S. FOOD AND DRUG ADMINISTRATION, *Orange Book Preface*, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm (last accessed Apr. 3, 2020).

medication guides, Defendants, as generic manufacturers of Metformin, made representations and express or implied warranties to third-party payers of the "sameness" of their products to branded MCDs, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels, medication guides, or were not adulterated or contained no other active pharmaceutical ingredients.

88. On information and belief, each Defendant affirmatively misrepresented and warranted to third-party payers through their websites, brochures, and other marketing or informational materials that their Metformin product complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

89. The presence of NDMA in Defendants' Metformin: (1) renders Defendants' Metformin products non-bioequivalent (that is, not the same) to branded MCDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result gross deviations from cGMPs thus rendering Defendants' Metformin products non-therapeutically equivalent to branded MCDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' Metformin containing an ingredient that is not also contained in branded MCDs, 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, or negligently failed to ensure their Metformin products' labels and other advertising or marketing statements accurately conveyed information about their products.

90. At all relevant times, Defendants have also impliedly warranted that their Metformin products were merchantable or fit for their ordinary purposes.

91. Due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Metformin. The presence of NDMA in Defendants' Metformin means that Defendants have violated implied warranties to Plaintiff and Class Members. The presence of NDMA in Defendants' Metformin results in Defendants' Metformin products being non-merchantable and not fit for its ordinary purposes (that is, as a therapeutically interchangeable generic version of branded MCDs), breaching Defendants' implied warranty of merchantability or fitness for ordinary purposes.

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

93. Adulterated Metformin is worthless. No third-party payer would have purchased or made a reimbursement for a purchase of an adulterated Metformin product or is even allowed to purchase adulterated Metformin product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Metformin products or competing medications with the same approved indications were available from other manufacturers.

94. Further, each Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated or misbranded, or both) drugs. Aurobindo, Heritage, and John Does each knew or should have known, based on information provided or available from each manufacturer or wholesaler, of the actual or potential adulteration, misbranding, or contamination of MCDs they purchased from manufacturer defendants.

9. John Doe Wholesalers

95. Defendants John Does 1-100 constitute one or more wholesalers that distributed adulterated, misbranded, or unapproved MCDs that were ultimately purchased by Plaintiff's assignors and other class members. The true names, affiliations, or capacities of John Doe Wholesalers are not presently known. However, each John Doe proximately caused damages to Plaintiff and class members as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Complaint when evidence from discovery reveals their identities.

96. Each Wholesaler John Doe Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated or misbranded, or both) drugs. Wholesaler Defendants knew or should have known, based on information provided or available from each manufacturer defendant, of the actual or potential adulteration, misbranding, or contamination of metformin they purchased from manufacturer defendants. Wholesaler Defendants expressly or impliedly warranted metformin they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.

FRAUDULENT CONCEALMENT AND TOLLING

97. Plaintiff and Class Members causes of action accrued on the date the Valisure CP was filed, or has not even accrued yet legally.

98. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of Defendants' cGMP violations with respect to Metformin, and of the fact that their Metformin products were adulterated and contaminated with NMDA, and were not the same as branded MCDs.

99. No Defendant revealed to the public that their Metformin product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to branded MCDs.

100. To the contrary, each Defendant continue to represent and warrant that their generic Metformin products were the same as and therapeutically interchangeable with branded MCDs by their failure to recall them.

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

102. 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 other Class Members exercised reasonable diligence by among other things promptly investigating and bringing this action. Despite these or other efforts, Plaintiff were unable to discover, and could not have discovered, the unlawful conduct alleged at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

THE REPRESENTATIVE ASSIGNMENT AGREEMENTS

103. 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.

104. 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.

105. 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**, states as follows:

> [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.

106. 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**

107. 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**, states as follows:

> 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.

108. Defendants have manufactured and distributed Metformin drugs throughout the United States, for which Plaintiff's assignors paid approximately $124 million on behalf of their enrollees. On information and belief, Plaintiff's assignors' payments include those payments for

Defendants' contaminated Metformin drugs, which were also manufactured, distributed, and sold during that same period.

CLASS REPRESENTATION ALLEGATIONS

109. 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 Defendants for itself and on behalf of the Class.

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

Nationwide Class as to All Counts Except Count IV

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

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

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

A. Federal Rule of Civil Procedure 23(a)

111. 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

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

(2) Commonality

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

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

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

(b) Whether each Defendant affirmatively misrepresented or omitted facts that its Metformin product was the same as branded MCDs and thus therapeutically interchangeable;

(c) Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs or was not adulterated;

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

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

(f) Whether the Defendants have been unjustly enriched;

(g) Whether the Defendants breached express and implied warranties;

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

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

(j) Whether Defendants fraudulently concealed Plaintiff's and Class Members' causes of action.

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

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

(3) Typicality

117. 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.

118. Plaintiff's claims are typical because the Defendants, through their misrepresentations and omissions, caused Plaintiffs and the Class Members to pay for adulterated and contaminated Metformin for which Plaintiff and the Class never should have had to pay. Plaintiff's claims also are typical because the 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 Metformin rugs were in compliance with cGMPs, and were merchantable and fit for their intended purpose when, in fact, they were not.

(4) Adequacy of Representation

119. 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.

120. 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)

121. 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 Defendants' common course of unlawful conduct. The predominating questions of law and fact include those set forth above in Paragraph 115.

122. 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.

123. 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.

124. 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 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
Breach of Express Warranty
(Against all defendants)

125. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

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

127. The Defendants sold the Metformin drugs, which they expressly represented and warranted were compliant with cGMPs and not adulterated or contaminated.

128. The Metformin drugs did not conform to the 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.

129. At all times when the Defendants marketed and sold the Metformin drugs, they knew the purposes for which the drugs would be used, and expressly warranted that the products were the same as branded MCDs, 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 Defendants' Metformin drugs in their formularies.

130. The Defendants breached their express warranties with respect to their Metformin drugs because the drugs did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to branded MCDs, and could not lawfully be sold.

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

132. Plaintiff's damages include their assignors' payments for defendants' Metformin drugs that did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to branded MCDs, and could not lawfully be sold.

COUNT II
Breach of Implied Warranties of Merchantability and Fitness,
(Against all Defendants)

133. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

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

135. The Metformin drugs are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

136. The Defendants were obligated to provide Plaintiff and the other Class Members reasonably fit Metformin 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 Metformin drugs were of fit and merchantable quality.

137. The Defendants knew, had reason to know, and should have known that their Metformin drugs were being manufactured and sold for the intended purpose of human consumption as a safe alternative to, and the bioequivalent of, branded MCDs, and impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

138. The Defendants breached their implied warranties, because their Metformin drugs were not of merchantable quality, nor fit for their ordinary purpose, and did not conform to applicable cGMPs.

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

140. Plaintiff's damages include their assignors' payments for defendants' Metformin 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 branded MCDs, could not lawfully be sold, and were so unmerchantable and unfit for their ordinary use as to have zero market value.

COUNT III
Fraud/Negligent Misrepresentation
(Against all defendants)

141. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

142. 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' Metformin drugs.

143. Defendants affirmatively misrepresented material facts, including the material

misrepresentations that their Metformin drugs were therapeutically equivalent and bioequivalent to MCDs, that those drugs complied with cGMPs, could lawfully be sold, and were not adulterated or contaminated.

144. Defendants failed to disclose the material facts that their Metformin drugs were not therapeutically equivalent and bioequivalent to MCDs, did not comply with cGMPs, could not lawfully be sold, and were adulterated or contaminated.

145. Defendants' misrepresentations fraudulently induced Plaintiffs' assignors and Class Members to include the Defendants' Metformin drugs in their formularies, which were used as the basis for causing them to pay for the Metformin drugs. Defendants knew, had reason to know, or should have known that the Metformin drugs were not therapeutically equivalent and bioequivalent to MCDs, that the drugs did not comply with cGMPs, 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' Metformin drugs if they had known the truth.

146. 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.

147. 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' Metformin drugs.

148. Defendants' misrepresentations and omissions were material.

149. Defendants made their misrepresentations and omissions with the intent to induce Plaintiff's assignors and the Class Members to pay for Defendants' Metformin drugs.

150. But for Defendants' misrepresentations and omissions, Plaintiff's assignors and

the Class Members would not have paid for Defendants' Metformin drugs.

151. 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' Metformin drugs in their formulary, nor paid any amount of money for the Metformin drugs.

152. Plaintiff and the Class Members have been damaged by Defendants' misrepresentations and omissions as alleged here.

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

153. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

154. 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.

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

156. 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.

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

158. Defendants made false and fraudulent misrepresentations that their Metformin drugs were compliant with cGMPs, were bioequivalent to MCDs, and could lawfully be sold. Defendants' failure to comply with cGMPs rendered the Metformin 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).

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

160. Plaintiff's and the Class Members' damages include, but are not limited to, all payments made for the Metformin drugs.

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

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

163. 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 V
Magnuss-Moss Warranty Act
15 U.S.C. § 2301, *et seq.*
(Against all defendants)

164. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

165. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

166. Plaintiff and other Class Members are "consumers" within the meaning of the

Magnuson-Moss Warranty Act.

167. Each Defendant expressly or impliedly warranted their Metformin drugs as alleged in the First and Second Causes of Action.

168. Under 15 U.S.C. § 2310(d)(1), Plaintiff and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract," and "may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues under this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

169. No Defendant has acted on the opportunity to cure its failure with respected to its warranted Metformin drugs.

170. Should Plaintiff prevail, it is entitled to receive an award of attorneys' fees and expenses under this section.

COUNT VI
Unjust Enrichment
(Against all defendants)

171. Plaintiff incorporates by reference paragraphs 1 to 124 of this Complaint.

172. Plaintiff's assignors and Class Members conferred a benefit on Defendants by promptly paying for the Metformin drugs they purchased.

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

174. Defendants knowingly and voluntarily accepted payments from Plaintiff's assignors and the Class Members for adulterated, contaminated Metformin drugs, which the Defendants fraudulently represented as therapeutically equivalent and bioequivalent to MCDs,

but did not comply with cGMPs, could not lawfully be sold, and were adulterated or contaminated.

175. It would be unjust and inequitable for the Defendants to retain the monies that Plaintiff's assignors and the Class Members paid for the worthless Metformin drugs.

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

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

178. 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 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, and unjust enrichment;

ii. awards Plaintiff and the Class Members attorneys' fees and expenses under applicable law; and

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

Dated: April 3, 2020.

RIVERO MESTRE LLP

Counsel for MSP Recovery Claims, Series LLC and the Class
2525 Ponce de León Blvd., Suite 1000
Miami, Florida 33134
Telephone: (305) 445-2500
Facsimile: (305) 445-2505
E-mail: arivero@riveromestre.com
E-mail: jmestre@riveromestre.com
E-mail: arolnick@riveromestre.com
E-mail: cwhorton@riveromestre.com
E-mail: ddaponte@riveromestre.com
Secondary: npuentes@riveromestre.com

By: /s/ Jorge A. Mestre
JORGE A. MESTRE
Florida Bar No. 088145
ANDRÉS RIVERO
Florida Bar No. 613819
ALAN H. ROLNICK
Florida Bar No. 715085
CHARLES E. WHORTON
Florida Bar No. 46894
DAVID L. DAPONTE
Florida Bar No. 1002724