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

JACQUELINE HARRIS, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

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

Defendants.

Civil Action No.:_____

Jury Trial Demanded

Complaint-Class Action

CLASS ACTION COMPLAINT

Plaintiff Jacqueline Harris ("Plaintiff"), individually and on behalf of all others similarly situated, brings this action against Aurobindo Pharma Ltd., Aurobindo USA, Inc., Aurolife Pharma, LLC, Heritage Pharmaceuticals, Inc., Emcure Pharmaceuticals, Rite-Aid Corporation, and John Does 1-1-100 ("Defendants"). Plaintiff's allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Plaintiff brings this action on behalf of herself and hundreds of thousands of other

metformin consumers who paid for Defendants' generic Metformin that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA").

2. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Metformin products were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

3. However, for years, Defendants willfully flouted federal current Good Manufacturing Practices ("cGMPs") and ignored other warnings signs that Defendants' Metformin products contained or likely contained NDMA and/or other impurities.

4. Metformin is a first-line diabetes treatment and is often referred to as the "gold standard" of diabetes management, and has been generic for decades. Defendants' adulterated Metformin products were illegally introduced into the American market for Defendants to profit from their sale to American consumers, such as Plaintiff and Class Members.

5. Plaintiff and Class Members paid for all or part of their Metformin prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since the beginning of their flagrant and serious cGMP violations that resulted in the NDMA contamination. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. PARTIES

6. Plaintiff Jacqueline Harris is a citizen and resident of New Jersey, who resides and is domiciled in Bridgeton, New Jersey. During the class period, Plaintiff paid money for one or more of Defendants' Metformin products. Defendants expressly and impliedly warranted to Plaintiff Harris that their respective generic Metformin products were the same as branded

metformin containing drugs ("MCDs"). Had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Harris would not have paid for Defendants' Metformin products.

7. 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 and/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 the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

8. 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 the manufacturing, sale, and distribution of MCDs in the United States.

9. 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 the manufacturing, sale, and distribution of MCDs in the United States.

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

11. 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. Upon information and belief, Heritage Pharmaceuticals is a subsidiary of India-based Defendant Emcure Pharmaceuticals.

12. Defendants Emcure Pharmaceuticals ("Emcure") is a foreign corporation with its principal place of business in Pune, India. Emcure on its own and/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 the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States. Upon information and belief, Emcure is responsible for the manufacture of MCDs sold by or through Heritage Pharmaceuticals in the United States. Upon information and belief, Heritage Pharmaceuticals is a only involved in the sales and marketing of Emcure's MCDs in the United States. These two entities, together, will be referred to as "Heritage."

13. Defendant Rite-Aid Corporation ("Rite-Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. At all times material to this case, Rite-Aid has been engaged in the sale and distribution of adulterated and/or misbranded MCDs in the United States.

III. JURISDICTION AND VENUE

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

15. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in New Jersey (and the United States generally), and otherwise

intentionally avails themselves of the markets within these states through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

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

IV. FACTUAL ALLEGATIONS

A. Metformin Background

17. 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.

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

19. In 2016, Metformin was the fourth-most prescribed medicine in the United States, with more than 81 million prescriptions dispensed.

B. The Generic Drug Approval Framework

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

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

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

products. 21 C.F.R. § 320.1(e).

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

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

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

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

27. According to the FDA, there are more than twenty (20) ANDAs approved for

Metformin.

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

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

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

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

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

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

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

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

21 C.F.R. § 211.22(a).

D. <u>The Valisure Citizen Petition</u>

33. Valisure is an online pharmacy licensed in thirty eight (38) 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.

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

35. On or about 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.

36. 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[.]"

37. Specifically with regard to generic Metformin products manufactured by

Aurobindo and Heritage, Valisure's testing (which closely followed the FDA own analytical methods) 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.[1]

38. Although the FDA has consistently stated that no levels of NDMA should be present in prescription drugs, it has set an interim safety limit of 96 ng/day purely out of drug shortage fears if all such products were recalled.

E. Background on NDMA

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

40. The WHO's IARC classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

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

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

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

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

[1] Heritage Metformin products are typically taken two to four times daily resulting in 532 ng to 904 ng of NDMA. Aurobindo Metformin products are typically taken four times daily resulting in 148 ng of NDMA.

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

immediately.

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

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

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

47. 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.

F. Aurobindo's cGMP Failures

48. As noted in the Valisure Citizen's Petition, "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.

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

50. 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 pursuant to federal law.

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

52. 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."

53. 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."

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

55. 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."

56. 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."

57. 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." Lastly, "[a]ppropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."

58. 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.

59. 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."

60. Additionally, 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 and/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.

61. 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.

62. 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.

63. 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, Aurobdino'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, and/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.

G. Heritage's cGMP Failures

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

65. Upon information and belief, Heritage has repeatedly violated and ignored such obligations and quality assurance standards.

66. With respect to Heritage's manufacturing practices, Defendant Emcure has been investigated by the FDA no fewer than 31 times since 2005.

67. 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.

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

69. 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."

70. 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.

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

72. 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.

73. 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.

74. 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, and/or met the quality and purity characteristics, which Heritage's MCDs purported to represent. As a result, Heritage willfully and recklessly introduced contaminated, adulterated and/or misbranded metformin containing products into the U.S. market.

H. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Metformin Products

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

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

Equivalence Evaluations" commonly referred to as the Orange Book.[3] The Orange Book is a public document; Defendants sought and received the inclusion of their products 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 to branded MCDs, Defendants were required to demonstrate that their generic Metformin products were bioequivalent to branded MCDs.

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

78. By introducing their respective Metformin products into the United States market under the name "Metformin" as a therapeutic equivalent to branded MCDs and with the FDA-approved label that is the same as that of branded MCDs, Defendants represent and warrant to end users that their products are in fact the same as and are therapeutically interchangeable with branded MCDs.

79. In addition, each Defendant's Metformin product is accompanied by an FDA-approved label and/or medication guide (aka patient leaflet or patient information). By presenting consumers with FDA-approved Metformin labels and/or medication guides, Defendants, as generic manufacturers of Metformin, made representations and express or implied warranties to consumers 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, and/or were not adulterated or contained no other active

[3] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Mar 3, 2020).

ingredients other than those reflected in the FDA-approved labels and/or medication guides.

80. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their websites, brochures, and other marketing or informational materials that their 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.

81. The presence of NDMA in Defendants' Metformin: (1) renders Defendants' Metformin products non-bioequivalent (*i.e.*, 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, and/or negligently failed to ensure their Metformin products' labels and other advertising or marketing statements accurately conveyed information about their products.

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

83. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in 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 (i.e.,

as a therapeutically interchangeable generic version of branded MCDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

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

85. Adulterated Metformin is essentially worthless. No consumer would purchase 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.

86. Further, each Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs. Aurobindo, Heritage, Rite-Aid, 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. Retail Pharmacy Defendants expressly or impliedly warranted MCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.

I. Rite-Aid and John Doe Wholesaler and Dispensing Entities

87. Defendant Rite Aid sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers during the class period as defined below.

88. Defendants John Doe 1-100 constitute one or more additional pharmacies and/or wholesalers that distributed adulterated, misbranded, and/or unapproved MCDs that were ultimately purchased by Plaintiff and other consumer class members. The true names, affiliations, and/or capacities of John Doe Pharmacies and 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.

89. Rite-Aid, as well as each Wholesaler John Doe Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs. Rite-Aid and 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. Rite-Aid and Wholesaler Defendants expressly or impliedly warranted metformin they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.

J. Fraudulent Concealment and Tolling

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

91. 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.

92. For instance, no Defendant revealed to the public that their Metformin product contained NDMA or was otherwise adulterated or non-therapeutically equivalent to branded MCDs.

93. 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.

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

95. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

K. Plaintiff Jacqueline Harris Individual Facts

96. Plaintiff Jacqueline Harris is a citizen and resident of Bridgeton, New Jersey.

97. Plaintiff Harris received Metformin products including but not limited to the following from Rite-Aid: (i) NDC 23155010205 Heritage Pharmaceuticals Inc 5/27/2017; (ii) NDC 65862000801 Aurobindo 3/22/2015The generic Metformin purchased by or dispensed to Plaintiff Harris manufactured by Defendants was not therapeutically equivalent to branded MCDs, was manufactured out of compliance with cGMPs, and was adulterated by its contamination with NDMA.

98. Defendants' generic Metformin was dispensed illegally to Plaintiff Harris.

V. CLASS ACTION ALLEGATIONS

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

> All individuals in the United States of America and its territories and possessions who, since January 1, 1995, paid part or all of the purchase price, for personal consumption or for a family or household member, of a generic metformin product manufactured by or for Defendants.

100. In the alternative, Plaintiff alleges sub-classes for all individuals in each State, territory, or possession (including specifically New Jersey) who, since at least January 1, 1995, paid part or all of the purchase price, for personal consumption or for a family or household member, of a generic metformin product manufactured by or for Defendants. Collectively, the foregoing Nationwide Class and alternative state sub-class are referred to as the "Class."

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

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

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

104. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of Metformin consumers

nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

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

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

b. Whether each Defendant's Metformin product was in fact the same as branded MCDs consistent with such express or implied warranties;

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

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

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

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

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

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

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

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

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

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

interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as all other Class Members.

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

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

109. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiff. Plaintiff's counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

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

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

111. Plaintiff, and each member of the Class, formed a contract with Defendants at the time Plaintiff and the other Class members purchased the MCDs. The terms of the contract include the promises and affirmations of fact made by Defendants on the MCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

112. Each Defendant expressly warranted that its MCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

113. Each Defendant sold MCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

114. Each Defendant's MCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

115. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat.

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

116. At the time that each Defendant marketed and sold its MCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members including but not limited to express representations made in referring to their MCDs as "metformin."

117. Each Defendant breached its express warranties with respect to its MCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

118. Plaintiff and each member of the Class would not have purchased the MCDs had they known these drugs were not the same as the RLD, did not contain the same ingredients, did not have the same safety and efficacy profile of the RLD, and contained NDMA.

119. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

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

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

121. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314;

N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

122. Defendants were all merchants within the meaning of the above statutes.

123. Defendants' MCDs drugs constituted "goods" or the equivalent within the meaning of the above statutes.

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

125. Each Defendant knew or should have known that its MCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their MCDs were of merchantable quality and fit for that purpose.

126. Each Defendant breached its implied warranty because each Defendant's MCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

127. Plaintiff and other Class members purchased the MCDs in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

128. The MCDs were not altered by Plaintiff or Class members.

129. As a direct and proximate result of each Defendant's breach of warranty, Plaintiff

and other Class Members have been injured and suffered damages, in that Defendants' MCDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

THIRD CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

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

131. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

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

133. Plaintiff and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

134. Each Defendant expressly or impliedly warranted their MCDs as alleged in the First and Second Causes of Action.

135. Under 15 U.S.C. § 2310(d)(1), Plaintiffs 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, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

136. No Defendant has acted on the opportunity to cure its failure with respected to its warranted MCDs.

137. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action,

Plaintiff is entitled to receive an award of attorneys' fees and expenses and pray for the same.

FOURTH CAUSE OF ACTION
FRAUD
(AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

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

139. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

140. Defendants affirmatively misrepresented material facts including, *inter alia*, that their MCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

141. Defendants omitted material facts including, *inter alia*, that their MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

142. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' MCDs – products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMPs and/or were adulterated and/or misbranded. Plaintiffs and other Class Members would not have purchased Defendants' MCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' MCDs had they known the truth because Defendants' MCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

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

representations false or misleading.

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

145. Defendants' misrepresentations and omissions were material.

146. Defendants' actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

147. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' MCDs.

148. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' MCDs.

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

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

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

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

152. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

153. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its MCDs.

154. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its MCDs.

155. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its MCDs.

156. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

157. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's MCDs.

158. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

159. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for MCDs.

160. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of MCDs, or had reckless disregard for same.

161. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendants' MCDs.

162. Plaintiff and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to

each Class Member.

163. Plaintiff and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

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

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

165. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

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

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

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

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

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

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

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus.

& Prof. Code §§ 17500, *et seq.*

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

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

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

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

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

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

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

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

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

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

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

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

or practices in violation of Kan. Stat. § 50-623, *et seq.*;

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

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

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

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

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

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

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

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

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

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

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

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

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

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

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

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

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

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

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

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

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

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

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

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

or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

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

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

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

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

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

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

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

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

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

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

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

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

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

168. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

169. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

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

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

171. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

172. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' MCDs.

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

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

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

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

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

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

177. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

178. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

179. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

180. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of MCDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

181. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own MCDs. Each Defendant knew that ignoring the manufacturing

issues surrounding its MCDs would damage Plaintiffs and the Class and increase its own profits.

182. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its MCDs complied with cGMPs and was not adulterated or misbranded.

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

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

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

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

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

187. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

188. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs.

189. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

190. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory,

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

191. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

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

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

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

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

195. As a proximate result of Defendants' acts and omissions, the Class is at an increased risk of developing cancer above the normal base-level risk.

196. As alleged above, Defendants' MCDs were contaminated with NDMA and/or other agents known to cause cancer in humans.

197. The Class Members may not develop cancer for many years.

198. The Class Members are at an increased risk as they consumed and/or ingested Defendants' MCDs for extended periods of time, some as many as several years, and as a result were exposed to a contaminant.

199. Upon information and belief, and based upon the internal and external investigations now made public, the Class is at an increased risk as they were exposed to NDMA/NDEA.

200. NDMA is a hazardous, life-threatening, toxic substance that is known to cause cancer in humans.

201. The Class Members are at an increased risk of cancer as they were exposed to, consumed, and/or ingested Defendants' MCDs in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

202. The exposure was caused solely and proximately by Defendants' failure to adequately manufacture their MCDs to be therapeutically equivalent; their failure to address discrepancies in batches/doses of Metformin during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that their MCD product was safe for consumption and/or ingestion and therapeutically equivalent to Diovan.

203. Defendants had a duty to the Class Members to: ensure and warrant that their MCD product was indeed therapeutically equivalent to brand/RLD as claimed and advertised to the Class Members; to disclose to the Class Members any defect, contamination, impurity or other potential health hazard known or discoverable by Defendants; and to ensure that their MCD product was not safe, reliable, and non-hazardous for human consumption—its intended purpose.

204. As alleged above, Defendants' own negligent acts and omissions resulted in cancer, or an increased risk of developing cancer for all members of the Class. Cancer is a serious disease-causing life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to, guaiac-based fecal occult blood test (gFOBT), fecal immunochemical test (FIT), FIT-DNA test, Flexible Sigmoidoscopy, Colonoscopy, and CT Colonography (Virtual Colonoscopy).

205. Early detection of cancer in patients is one of the best, and sometimes the only

means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

206. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

207. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA-associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require more frequent screenings not within the purview of routine medical exams.

208. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.

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

and just.

210. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

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

212. Each Defendant owed a duty to Plaintiff and the Class to ensure that the MCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

213. Each Defendant owed a duty to Plaintiff and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

214. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

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

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

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following judgment:

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

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

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

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

E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the MCDs; the costs to replace or return MCDs because of recalls; Defendants' ill-gotten gains; and/or the increases in the amounts paid for non-adulterated, non-misbranded, MCDs in the wake of the recalls;

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

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

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

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

Dated: March 27, 2020

RESPECTFULLY SUBMITTED,

/s/ David J. Stanoch

Ruben Honik, Esquire (NJ Bar 027381980)
David J. Stanoch, Esquire (NJ Bar 012902003)
GOLOMB & HONIK, P.C.
1835 Market Street, Suite 2900
Philadelphia, PA 19103

Tel.: 215-965-9177
Fax: 215-985-4169
rhonik@golombhonik.com
dstanoch@golombhonik.com

Allan Kanner (NJ Bar 033981980)
Conlee S. Whiteley (LA Bar 22678)
(*pro hac vice to be filed*)
Layne Hilton (LA Bar 36990)
(*pro hac vice to be filed*)
Annemieke Tennis (LA Bar 37893)
(*pro hac vice to be filed)*
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, Louisiana 70115
Tel.: 504-524-5777
Fax: 504-524-5763
a.kanner@kanner-law.com
c.whiteley@kanner-law.com
l.hilton@kanner-law.com
a.tennis@kanner-law.com

John R. Davis (TX Bar 24099518)
(*pro hac vice to be filed*)
SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
jdavis@slackdavis.com

Daniel A. Nigh (FL Bar No. 30905)
(*pro hac vice to be filed*)
LEVIN, PAPANTONIO, THOMAS, MITCHEL, RAFFERTY & PROCTOR, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
Phone: (850) 435-7013
Fax: (850) 436-6013
dnigh@levinlaw.com

Counsel for Plaintiff and the Proposed Class