

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE: METFORMIN MARKETING  
AND SALES PRACTICES  
LITIGATION

Case No. 2:20-cv-2324-MCA-MAH

Hon. Madeline C. Arleo

Hon. Michael A. Hammer

**JURY TRIAL DEMANDED**

**FOURTH AMENDED CLASS ACTION COMPLAINT**

**REDACTED VERSION**

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Consumer and Third Party Payor (“TPP”) Plaintiffs (collectively, “Class Plaintiffs”), by and through their undersigned counsel, bring this action individually and on behalf of all others similarly situated, and seek to recoup their losses for payments or made reimbursements they and the class made for generic metformin-containing drugs that were illegally and willfully manufactured, distributed, and/or introduced into the market by Defendants (as defined herein).

### **INTRODUCTION**

1. This case arises the sale of adulterated, misbranded, and unapproved metformin-containing drugs (“MCDs”) that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Defendants (identified and defined below at Part II.C-H), in the United States, and that have been subject to one of the largest ongoing contaminated drug recalls in the United States. These MCDs are non-merchantable and are not of the quality represented by Defendants.

2. Metformin, originally marketed under the brand name Glucophage and/or Glucophage XR, 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.

3. Metformin was discovered in 1922, and first marketed in the United States in 1995. Metformin is considered so critical to diabetes management that it is listed by the World Health Organization (“WHO”) on its List of Essential Medicines.

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

5. Metformin Hydrochloride (“Metformin HCL”) is the generic version of Glucophage and/or Glucophage XR, a now-discontinued product made by EMD Serono,<sup>1</sup> which is the Reference Listed Drug (“RLD”).

6. At all pertinent times for this action, Defendants represented and warranted to consumers and TPPs that their generic MCDs were therapeutically equivalent to and otherwise the same as the RLD. Specifically, Defendants represented and warranted that the MCDs were fit for their ordinary uses, met the specifications of Defendants’ FDA-approved labeling materials, were manufactured and distributed in accordance with all applicable laws and regulations, and were not contaminated with any carcinogenic impurities.

7. For years, however, Defendants willfully ignored warnings about the operating standards at several of the overseas manufacturing plants where Defendants’ generic MCDs were manufactured for import to the United States, and

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<sup>1</sup> EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany.

knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded MCDs which were purchased and/or reimbursed by Plaintiffs and the class throughout the United States.

8. Specifically, Defendants' MCDs were adulterated and/or misbranded (and thereby rendered worthless) through contamination with a probable human carcinogen known as N-nitrosodimethylamine ("NDMA") and were otherwise substandard to the Metformin HCL originally approved by the U.S. Food and Drug Administration ("FDA").<sup>2</sup> Accordingly, Defendants' representations that their generic MCDs were therapeutically equivalent to and otherwise the same as the RLD are false because the generic MCDs are contaminated with NDMA, and likely have been for many years prior.

9. Because the NDMA was the result of a manufacturing issue, upon information and belief, each and every one of lots of Defendants' MCDS were contaminated with NDMA. In addition, when a drug is manufactured in a non-cGMP compliant manner, the manufacturer cannot assure that the drugs meet the appropriate quality, purity, identity, or strength. Accordingly, such drugs are adulterated, misbranded, or both. Because a manufacturing process failure and

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<sup>2</sup> The International Agency for Research on Cancer ("IARC") and the U.S. Environmental Protection Agency ("EPA") both list NDMA as a probable human carcinogen.

testing/quality assurance failure lay at the heart of Defendants' process for making MCDs, these products were not made in a cGMP-compliant manner, which rendered the products adulterated and/or misbranded, and therefore unsellable and worthless, whether or not a given pill contained NDMA or not. *See, e.g.*, 21 U.S.C. § 351; *see also* 21 U.S.C. § 331.

10. According to FDA testing, the generic MCDs subject to this action contained NDMA contamination levels many times higher than the FDA's February 28, 2019 updated interim limits for NDMA impurities. The FDA has yet to release testing results for other nitrosamine impurities.

11. Upon information and belief, the NDMA contamination of Defendants' MCDs dates back many years, at which point Defendants had actual and/or constructive notice of the contamination.

12. Plaintiffs paid for and consumed (in the case of Consumers), and paid for or reimbursed payment of (in the case of TPPS), contaminated MCDs that were illegally placed into the stream of commerce by Defendants.

13. Plaintiffs paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants, which caused them and the millions of other MCD consumers, as well as TPPs, to sustain economic damages as a result of paying for generic MCDs that were falsely represented to be

the equivalent of the RLDs, but were not as a result of the NDMA contamination and/or the cGMP failures in the manufacture of the generic MCDs.

14. Plaintiffs and the Class paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants as a result of paying for generic MCDs that were adulterated and/or misbranded because they were not made in a cGMP-compliant manner (whether or not a particular pill contained NDMA or not).

15. Defendants' generic MCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs. Defendants' conduct, as detailed in this Second Amended Consolidated Economic Class Action Complaint ("Master Class Complaint"), also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law.

## **THE PARTIES**

### **I. THE CONSUMER PLAINTIFFS**

16. Plaintiff Joseph Brzozowski is a citizen and resident of New Jersey.

17. Plaintiff Michael Hann is a citizen and resident of California.

18. Plaintiff Jacqueline Harris is a citizen and resident of New Jersey.

19. Plaintiff Kristin Wineinger is a citizen and resident of Indiana.

20. Plaintiff Masao Hendrix is a citizen and resident of California.

21. Plaintiff Marcia Brice is a citizen and resident of Florida.

## **II. THE THIRD-PARTY PAYOR (“TPP”) PLAINTIFFS**

22. Plaintiff MSP Recovery Claims, Series LLC (“MSPRC”) is a Delaware series limited liability company with its principal place of business at 2701 S. Lejeune Road, 10th Floor, Coral Gables, Florida 33134. MSPRC’s limited liability company agreement provides for the establishment of one or more specific series. All records of all series are maintained together with all assets of MSPRC.

23. Plaintiff County of Monmouth is located in Freehold, New Jersey. County of Monmouth is a county and public entity organized and existing pursuant to Title 40 of the Laws of the State of New Jersey and is a citizen of the State of New Jersey.

24. Plaintiff Ohio Carpenters’ Health Fund (“Ohio Carpenters’”) is located in Troy, Michigan. Ohio Carpenters’ is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. Ohio Carpenters’ is also a multiemployer, collectively bargained trust fund established in accordance with LMRA §302(c)(5), 29 U.S.C. §186(c)(5), for the purpose of providing benefits for employees and their beneficiaries.

## **III. THE MANUFACTURER DEFENDANTS**

25. For ease of reading, this Complaint generally organizes Defendants by the distribution level at which they principally operate. The following Defendants

manufacture the active pharmaceutical ingredient (“API”) for Defendants’ MCDs or are closely affiliated with an entity that does so. Including certain Defendants in this section does not mean they are not properly classifiable as another type of defendant, or vice versa (*e.g.*, a Defendant listed in this subsection may also be a distributor; a Defendant listed in the distributor subsection may also be an API manufacturer).

**A. The Teva/Actavis Entities**

26. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva”). At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic MCDs in the United States.

27. Actavis Pharma, Inc. (“Actavis Pharma”) is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva’s wholly-owned subsidiary. At all times material to this case, Actavis Pharma has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

28. Actavis LLC (“Actavis”) is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva’s wholly owned subsidiary. At all times material to this case, Actavis has been

engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States. Teva USA, Actavis Pharma, and Actavis are collectively referred to as the Teva Defendants in this Master Class Complaint.

**B. The Avet/Granules Entities**

29. Defendant Heritage Pharmaceuticals, Inc. d/b/a Avet Pharmaceuticals Inc. (hereinafter “Avet” or “Heritage”) is a corporation incorporated under the laws of Delaware with a principal place of business at One Town Center Boulevard, East Brunswick, New Jersey 08816.

30. Defendant Granules USA, Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 35 Waterview Boulevard, Parsippany, New Jersey 07054. Granules USA, Inc. is a wholly-owned subsidiary of the Indian corporation Granules India Limited. Granules USA, Inc. has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

31. Defendant Granules Pharmaceuticals, Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 3701 Concorde Parkway, Chantilly, Virginia 20151. Granules Pharmaceuticals, Inc. is a wholly owned subsidiary of the Indian corporation Granules India Limited. Granules Pharmaceuticals, Inc. has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

32. On or about 2007, Heritage and Granules entered into a strategic alliance for the development, supply and marketing of generic pharmaceutical products, including MCDs, for the U.S. prescription drug market. Under the agreement, Granules develops and registers selected products for ANDA submission and Heritage retains exclusive sales and marketing rights to such products. Under the arrangement, Granules receives up front and milestone payments and the parties share net profits from the product sales.

33. At the time, Heritage's then-chief executive, Jeffrey Glazer, said: "[Heritage's] partnership with Granules represents another important milestone in Heritage's business model of utilizing strategic outsourcing for the development and manufacturing of quality generic products. Granules PFI technology represents a significant cost advantage for high-load, high-volume generic products, and will provide us with unprecedented economies of scale for the products under our agreement."

### **C. The Amneal Entities**

34. Defendant Amneal Pharmaceuticals, Inc. ("Amneal") is a Delaware corporation with its principal place of business at 400 Crossing Blvd., Bridgewater Township, NJ 08807. At all times material to this case, Amneal has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States.

35. Defendant Amneal Pharmaceuticals LLC is a corporation incorporated under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. Amneal conducts substantial business in the United States, and specifically in the States of New Jersey and California. Amneal has been engaged in the manufacturing, distribution, and sale of defective MCDs throughout the United States.

36. Defendant Amneal Pharmaceuticals of New York, LLC is a New York limited liability company with its principal place of business at 75 Adams Avenue, Hauppauge, New York, USA 11788. Amneal Pharmaceuticals of New York conducts substantial business in the United States and has been engaged in the manufacturing, distribution, and sale of defective metformin in the United States.

#### **IV. THE RETAIL PHARMACY DEFENDANTS**

37. Retail pharmacies have supply arrangements with manufacturers. They stand in direct contractual privity with consumers, given that retail pharmacies (be they brick-and-mortar or mail-order) are the entities that dispensed and received payment for the adulterated and/or misbranded MCDs for which consumers paid and TPPs reimbursed. The following Defendants are collectively referred to as the “Pharmacy Defendants.”

**A. CVS**

38. Defendant CVS Health Corporation (“CVS Health”) is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895.

39. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

40. Defendant CVS Health sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs during the class period.

**B. Walmart**

41. Defendant Walmart Stores, Inc. (“Wal-Mart”) is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

42. According to Defendant Wal-Mart’s 2020 Form 10-K, Wal-Mart maintains approximately 4,756 retail locations in all fifty states nationwide, the District of Columbia, and Puerto Rico (including supercenters, discount stores, and neighborhood markets and other small format locations). Most or all of these locations have Wal-Mart health and wellness products and services, which includes prescription pharmaceutical services. There are another approximate 600 Sam’s

Club locations across the United States, all or nearly all offering prescription pharmaceutical services.

43. Defendant Wal-Mart (including Sam's Club) sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs across the country during the class period.

### **JURISDICTION AND VENUE**

44. 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.

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

46. Venue is proper in this District because of the MDL consolidation pursuant to 28 U.S.C. § 1391 and because Defendants reside in this District, “a substantial part of the events or omissions giving rise to the claim occurred” in this

District, and Defendants are subject to the personal jurisdiction of this Court. 28 U.S.C. § 1391(b)(3).

## **FACTUAL ALLEGATIONS**

### **I. GENERIC METFORMIN IS EXPECTED TO BE IDENTICAL TO ITS BRAND-NAME COUNTERPART, GLUCOPHAGE**

47. Metformin is the generic name for Glucophage.<sup>3</sup> Metformin is used to “treat[] type 2 diabetes” by regulating blood sugar and helping “your body use insulin effectively.”<sup>4</sup> A 500mg Metformin pill is meant to be taken once a day (with insulin) or twice a day (without).<sup>5</sup>

48. Metformin was “first used clinically in 1958 [and] is today the first choice or ‘gold standard’ drug for the treatment of type 2 diabetes and polycystic ovary disease.”<sup>6</sup> Indeed, Metformin is regarded as so critical to diabetes management that it is listed by the WHO on the WHO’s List of Essential Medicines.<sup>7</sup>

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<sup>3</sup> <https://my.clevelandclinic.org/health/drugs/20966-metformin-tablets>

<sup>4</sup> *Id.*

<sup>5</sup> <https://www.mayoclinic.org/drugs-supplements/metformin-oral-route/description/drg-20067074>

<sup>6</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC5588255/>.

<sup>7</sup> WHO HEALTH ORGANIZATION MODEL LIST OF ESSENTIAL MEDICINES, at 47 (2023), <https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1>

49. Between 2000 and 2015, “[a]n estimated 553,291,094 MET prescriptions were dispensed in the US.”<sup>8</sup> Between 2016 through 2022, approximately 80 million Metformin prescriptions were issued in the US per year.<sup>9</sup>

50. Generic approvals of Metformin Hydrochloride began occurring in the early 2000s after the expiration of Glucophage’s exclusivity period.

51. Because Metformin is a generic drug, those that manufacture, distribute, and sell generic Metformin expressly and impliedly warrant that the generic Metformin is the same as its brand-name counterpart, Glucophage. This is so for a number of reasons.

52. *First*, companies manufacturing brand-name drugs (*i.e.*, Glucophage) submit a New Drug Application (“NDA”) to the FDA and must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. §§ 355, *et seq.* By contrast, companies manufacturing generic drugs (*i.e.*, Manufacturer Defendants here, who manufactured generic Metformin) must only submit an Abbreviated New Drug Application (“ANDA”). With an ANDA, generic drug companies need only demonstrate “bioequivalence” to the generic Metformin to brand-name or Reference Listed Drug (“RLD”), Glucophage.

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<sup>8</sup> <https://pubmed.ncbi.nlm.nih.gov/31124014/>.

<sup>9</sup> <https://www.statista.com/statistics/780332/metformin-hydrochloride-prescriptions-number-in-the-us/>.

53. Bioequivalence is the “absence of significant difference” in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

54. “A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.”<sup>10</sup>

55. In other words, the theory is that (1) because Glucophage has been proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the Manufacturer Defendants have shown that their generic Metformin products are bioequivalent to Glucophage, then (3) generic Metformin is warranted to be safe and effective for the same approved indication as Glucophage.

56. *Second*, 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 at least the following: (i) the active ingredient(s) are the same as the brand-

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<sup>10</sup> <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>.

name drug (21 U.S.C. § 355(j)(2)(A)(ii)); and (ii) that the generic drug is “bioequivalent” to the brand-name drug and “can be expected to have the same therapeutic effect” (21 U.S.C. § 355(j)(2)(A)(iv)). A generic manufacturer must also make “a full statement of the composition of such drug” to the FDA. 21 U.S.C. § 355(j)(2)(A)(vi); *see also* 21 U.S.C. § 355(b)(1)(C).

57. *Third*, a generic manufacturer must submit information to show that the “labeling proposed for the new drug is the same as the labeling approved for the” brand-name counterpart. 21 U.S.C. § 355(j)(2)(A)(v).

58. In short, when a company like the Manufacturer Defendants label their drug as “Metformin,” they are representing the drug is *identical* to its brand-name counterpart, Glucophage, in safety and effectiveness. Indeed, pharmacists, physicians, and patients expect generic drugs to be therapeutically interchangeable with Glucophage.

59. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval—in other words, when the drug is not the same as its corresponding brand-name drug—then the manufacturer has created an entirely new and unapproved drug.

## II. NDMA IS A CARCINOGENIC COMPOUND

60. N-nitrosodimethylamine (“NDMA”) “is an organic compound that forms in both industrial and natural processes, and has been used to make liquid rocket fuel, softeners, and lubricants.”<sup>11</sup>

61. NDMA can form “by a nitrosating reaction between amines (secondary, tertiary, or quaternary amines) and nitrous acid (nitrite salts under acidic conditions).”<sup>12</sup>

62. “Under these conditions, nitrite salts may form nitrous acid, which can react with an amine to form a nitrosamine.”<sup>13</sup>

63. “Amines may be present in a manufacturing process for a variety of reasons. The API (or API degradants), intermediates, or API raw materials<sup>22</sup> may contain secondary or tertiary amine functional groups. Tertiary and quaternary amines may also be added intentionally as reagents or catalysts. All of these types of amines can react with nitrous acid or other nitrosating agents to form nitrosamines.”<sup>14</sup>

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<sup>11</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC6351967/>.

<sup>12</sup> <https://www.fda.gov/media/141720/download> at 4.

<sup>13</sup> *Id.* at 6.

<sup>14</sup> *Id.*

64. In addition, “[r]ecovered materials such as solvents, reagents, and catalysts may pose a risk of nitrosamine impurities due to the presence of residual amines (such as trimethylamine or diisopropylethylamine).”<sup>15</sup>

65. “NDMA has been studied in animals and found to increase the occurrence of cancer.”<sup>16</sup> Indeed, “[t]he US Environmental Protection Agency found an association between NDMA and liver toxicity, which could lead to liver cancer,” and “NDMA exposure may be associated with bladder, renal, pancreatic, intestinal, colon, and stomach cancers.”<sup>17</sup>

66. Similarly, as the CDC noted in its risk profile of NDMA, “[o]ral exposure to NDMA primarily induces liver and lung tumors in rats and mice and has also induced kidney tumors in these species and testicular tumors in rats. Increased incidences of liver tumors were also observed in hamsters and mink after oral exposure to NDMA.”<sup>18</sup>

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<sup>15</sup> *Id.* at 8.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> TOXICOLOGICAL PROFILE FOR N-NITROSODIMETHYLAMINE (NDMA) at 10 (2023), <https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf>.

67. The CDC further noted that “NDMA’s carcinogenicity is widely recognized,” including by “[t]he International Agency for Research on Cancer” and “the Department of Health and Human Services.”<sup>19</sup>

68. Anecdotally, NDMA has also been used in intentional poisonings.<sup>20</sup>

69. NDMA is not an ingredient of either Glucophage or generic Metformin and should not appear in Metformin if the drug is manufactured properly.

70. The FDA has recommended a daily limit of NDMA of no more than 96 nanograms per day.<sup>21</sup> A nanogram is one billionth of a gram. To put that in perspective, “[i]f you slice a single grain of rice into 25,000,000 parts,” “[o]ne of the 25,000,000 parts weighs 1 nanogram.”<sup>22</sup>

71. So, effectively, the FDA recommends limiting daily NDMA intake to 96 pieces of 1/25 million parts of a single grain of rice. That is innumerable small.

72. Primarily, however, the FDA recommends that “API manufacturers [] optimize the design of the manufacturing process for APIs during route of synthesis

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<sup>19</sup> *Id.* at 5.

<sup>20</sup> *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 June 5, 2019).

<sup>21</sup> <https://www.fda.gov/media/141720/download>.

<sup>22</sup> [https://www.metalscoalition.com/uploads/2/4/3/5/24359359/what\\_is\\_one\\_nanogram.pdf](https://www.metalscoalition.com/uploads/2/4/3/5/24359359/what_is_one_nanogram.pdf).

(ROS) development to minimize or prevent the formation of nitrosamine impurities. API manufacturers should refer to the recommendations in ICH M7(R2) and the ICH guidances for industry Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (September 2016) and Q11 Development and Manufacture of Drug Substances (November 2012) in this respect.”<sup>23</sup>

### **III. DEFENDANTS’ METFORMIN WERE ALL CONTAMINATED WITH UNSAFE LEVELS OF NDMA DUE TO UNIFORM MANUFACTURING DEFICIENCIES**

73. The extent of Defendants’ NDMA contamination and cGMP deviations are discussed below. As an overarching matter, as detailed more fully below for each pertinent Defendant, the NDMA contamination at issue here is a process-related impurity arising from the manufacture of the finished-dose MCDs. Because the NDMA was a process-related impurity – i.e., it was not isolated, a one-off accident, etc. – it is plausible and, under the weight of industry literature and guidance, reasonably expected that the every batch and every lot of finished product manufactured would experience the same cGMP deficiency.

74. Generally speaking, a process impurity is an unintended chemical entity or potential chemical reaction introduced during the manufacturing process. Such impurities generally originate from raw materials, catalysts, reagents, intermediates, environmental conditions, or by-products formed during synthesis. According to

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<sup>23</sup> <https://www.fda.gov/media/141720/download>.

ICH Guidance Q3A(R2), process (and degradation) impurities should be evaluated for their potential, characterized, monitored, and controlled or eliminated.

75. Process impurities are linked to the drug substance manufacturing process. According to ICH Guidance Q3A(R2), the impurity profile of a drug substance must be consistent between development and commercial manufacturing batches to ensure quality, and consistent uniformity (e.g., replication of product to specification). Since commercial manufacturing processes are validated for repeatability, process impurities present in the drug substance and carried over into the drug product during validation will also be present in all subsequent production batches.

76. Since pharmaceutical manufacturing ensures uniform mixing of active ingredients and general content uniformity, the distribution of any impurity already present in the drug substance is expected with certain assumptions to be also uniformly distributed in the drug product. Each manufacturer applying for approval of their NDA or ANDA must provide “a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing a such drug,” 21 U.S.C. § 355(b)(1)(D), which, when approved by the agency, necessarily demands and results in uniformity of the finished drug. Consequently, a defect in the controls used for manufacture, processing, and packing of such drug, will result in uniform contamination of the drug.

77. Regulatory agencies require drug manufacturers to establish scientifically justified specifications for impurities to ensure batch uniformity. According to 21 CFR Part 211, batch-to-batch consistency must be maintained through validated manufacturing processes, ensuring that any impurity identified in the drug substance and, carried through to drug product, persists predictably across all commercial batches.

78. The same principles and quality-by-design carry through to drug products. The entire framework of drug product manufacturing is to ensure repeatable consistency and within-specifications uniformity in the product manufacture.

79. Based on established regulatory guidelines, industry standards, and empirical data, it is reasonable to conclude that a process impurity, once present, will consistently appear in every batch of the finished drug product unless actively removed or degraded during formulation.

80. In other words, the manufacture of a drug product, such as MCDs, must by design, regulation, and expectation result in the routine, systematic production of like-quality products, such that both desired components as well as unwanted impurities are consistently, uniformly present in each product made during the common-by-design manufacturing process.

81. Therefore, an impurity such as NDMA – which as detailed *infra* resulted from a chemical reaction during a singular manufacturing process that utilizes by design the same components every time – would be widespread and systematically present in every product manufactured.

**A. Amneal’s Metformin Was Uniformly Contaminated With NDMA**

82. Amneal’s ANDA for generic Metformin Hydrochloride was purchased in January 2008 from Interpharm, which, upon information and belief, no longer exists.<sup>24</sup> Amneal, as of the purchase date, owned the ANDA and all representations made in it. By so registering, Amneal represented that any Metformin it manufactured, distributed, and/or sold was the bioequivalent of Glucophage.

83. During the relevant time period, Amneal manufactured and sold multiple metformin products.

84. Among these products were metformin ER products made and sold under regulatory approval were those with the ANDAs 077880 and 07896, which was the approval for both the 500mg, 750mg, 850 mg, and 1000 mg strength metformin ER products made by Amneal.

85. The above products were identical to each other, and made using the exact same manufacturing process. The only difference between the NDCs was the

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<sup>24</sup> [https://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=A&Appl\\_No=078596#27611](https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=078596#27611).

package size, i.e., either a 100-pill count or a 500-pill count. This is also indicated by the first eight digits of the NDCs being identical except for the last two digits of “01” or “05,” which merely denotes the pill count per bottle.

86. Being subject to the same regulatory approval, ANDAs 077880 and 07896, the above NDC products were manufactured using the same processes, materials, components, and conditions (e.g., metformin API, excipients, etc.).

87. In August 2017, Amneal

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

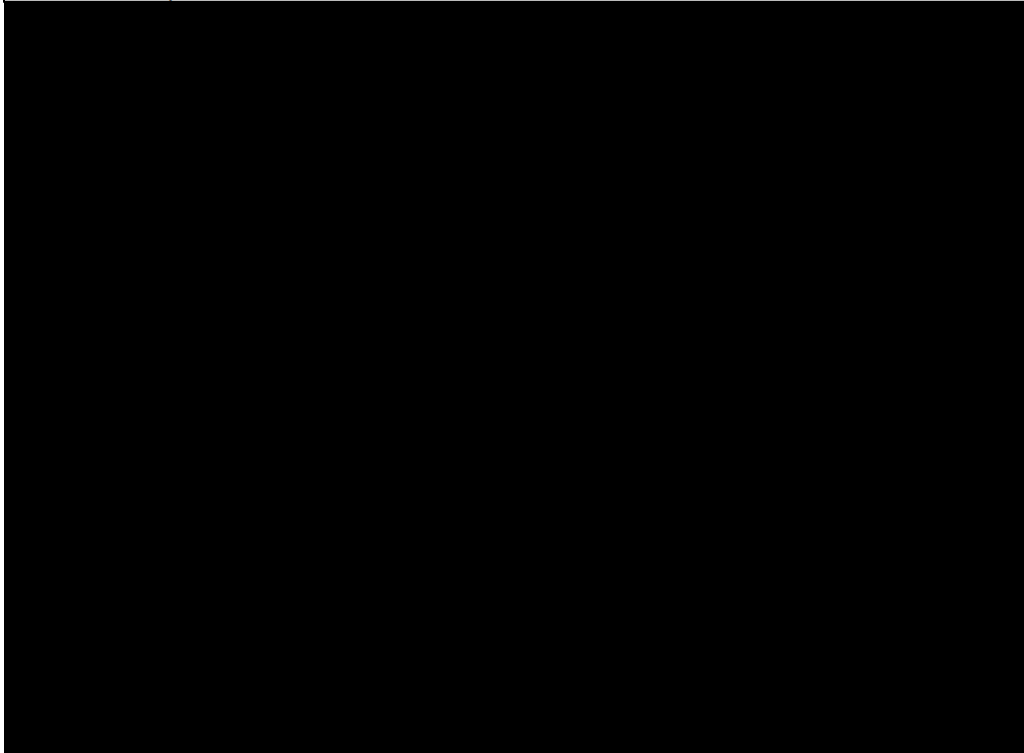
AMNEAL-

MET00259322.

[REDACTED]

88. Even as late as August 2018, Amneal [REDACTED]

[REDACTED] AMNEAL-MET00422833.



89. In September 2019, however, [REDACTED]



AMNEAL-MET00182913. [REDACTED]

[REDACTED] *See* AMNEAL-MET00170390.

90. In March 2020, Valisure performed independent testing on Amneal’s Metformin—among other Metformin products—regarding the potential presence of

NDMA. 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.

91. Valisure found levels of NDMA in numerous lots of Amneal’s Metformin at as much as *seventeen times* the daily acceptable limit, the highest of the products Valisure tested:

Company	Dose (mg)	Type	Lot	NDMA (ng/tablet)	Times Over Acceptable Daily Intake Limit of NDMA
Amneal Pharmaceuticals LLC	750	Metformin ER	AM180 770A	450 +/- 100	9.4X
Amneal Pharmaceuticals LLC	500	Metformin ER	AM180 770A	395 +/- 53 (623 +/- 28)* <sup>25</sup>	16.5X
Amneal Pharmaceuticals of New York LLC	500	Metformin ER	HD033 19A	283 +/- 27	11.8X
Amneal Pharmaceuticals of New York LLC	500	Metformin ER	HD029 18A	282 +/- 67	11.8X
Amneal Pharmaceuticals of New York LLC	850	Metformin IR	AM180 405A	235 +/- 17	4.9X

92. Valisure [REDACTED]

[REDACTED]

[REDACTED] AMNEAL-MET01633876. However, [REDACTED]

[REDACTED]

[REDACTED] AMNEAL-MET01380586-AMNEAL-MET01380589.

<sup>25</sup> The asterisk (\*) denotes data generated by Emery Pharma from the same batch.

93. In April 2020, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

AMNEAL-MET01589629.

[REDACTED]

*See also* AMNEAL-MET00000059.

94. Amneal [REDACTED]

[REDACTED]

[REDACTED]

AMNEAL-MET01589632. Hypromellose

is a compound that “provides the release of a drug in a controlled manner, effectively increasing the duration of release of a drug to prolong its therapeutic effect.”<sup>26</sup> In

other words, [REDACTED]

[REDACTED]

[REDACTED]

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<sup>26</sup> <https://pubmed.ncbi.nlm.nih.gov/15901342/>.

95. In May 2020,

[REDACTED]

AMNEAL-MET00000535.

96. In June 2020,

[REDACTED]

97. In addition,

- [REDACTED]

- [REDACTED]

98. The FDA [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

AMNEAL-MET01429341

99. Coinciding with this, in June 2020, Amneal issued a recall of “all lots within expiry of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg

and 750 mg.”<sup>27</sup> In this recall announcement, Amneal stated that it was “notified by the U.S. FDA that the Agency’s testing of seven lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, showed N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels. FDA recommended the recall of the seven tested lots.”<sup>28</sup> Notably as a result “Amneal [] agreed to this recall and has further decided to extend the recall to all lots within expiry of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg.”<sup>29</sup> Thus, any purchase of Amneal Metformin with NDC codes 53746-178-01, 53746-178-05, 53746-178-10, 53746-178-90, 53746-178-Bulk, 65162-178-09, 65162-178-10, 65162-178-11, 65162-178-50, 53746-179-01, 53746-179-Bulk, 65162-179-10 are presumed to be adulterated and contaminated.

100. Amneal also noted that “NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory

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<sup>27</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended>.

<sup>28</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended#recall-announcement>.

<sup>29</sup> *Id.*

tests,” and that “[a]nyone with an existing inventory of the product should quarantine the recalled lots immediately.”<sup>30</sup>

101. In July 2020, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

AMNEAL-MET-1429140 (emphasis added).

102. When Amneal [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

---

<sup>30</sup> *Id.*

AMNEAL-MET00001048.

103. Nonetheless, [REDACTED]

[REDACTED]

[REDACTED] AMNEAL-MET0000943.

104. In January 2021, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

AMNEAL-MET00001684.

105. Finally, in August 2021, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] AMNEAL-

MET00002787.

106. *Second*, [REDACTED]

[REDACTED]

[REDACTED]

107. In addition to the testing identified by Valisure in its Citizen Petition, [REDACTED]

[REDACTED]

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31 [REDACTED]

32 [REDACTED]

33 [REDACTED] 34 [REDACTED]

[REDACTED]

[REDACTED]

108. To summarize, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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33 [REDACTED]

34 [REDACTED]

**B. Teva’s Metformin Was Uniformally Contaminated With NDMA**

109. Teva Defendants’ manufacturing process for MCDs was systemically deficient to such an extent that all of its at-issue MCDs were contaminated with NDMA

110. During the relevant time period, Teva Defendants manufactured sold multiple metformin products.

111. Among these products were metformin ER products made and sold under two regulatory approvals ANDA076172 (500mg) and ANDA076869 (750mg).

112. Teva Defendants manufactured and sold MCDs during the relevant time period that bore the following with the following NDCs:

<b>NDC</b>	<b>Package Count</b>	<b>ANDA File Number</b>
<b>62037-577-01 (750 mg)</b>	<b>100 count bottles</b>	ANDA076869
<b>62037-577-10 (750 mg)</b>	<b>1000 count bottles</b>	ANDA076869
<b>62037-571-01 (500 mg)</b>	<b>100 count bottles</b>	ANDA076172
<b>62037-571-10 (500 mg)</b>	<b>1000 count bottles</b>	ANDA076172

113. The 750mg products (NDC 62037-577-01 and 62037-577-10), and the 500mg products (NDC 62037-571-01 and 62037-571-10), were identical to each other respectively, and made using the exact same manufacturing process. The only

difference between the NDCs for the two 750mg products, and for the two 500mg products, was the package size, i.e., either a 100-pill count or a 1000-pill count. This is also indicated by the first eight digits of the NDCs being identical except for the last two digits of “01” or “10,” which merely denotes the pill count per bottle.

114. The MCDs made under ANDA076869 and ANDA076172 were manufactured [REDACTED]

[REDACTED] All of the MCDs with the above-referenced NDCs – 62037-577-01, 62037-577-10, 62037-571-01, and 627037-571-10 – [REDACTED]  
[REDACTED]

115. The Valisure Citizen’s Petition specifically found NDMA in Teva Defendants’ at-issue MCDs bearing NDC 62037-571-01 and 62037-577-10.

116. In April 2020, [REDACTED]  
[REDACTED]  
[REDACTED]

117. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

118. In May 2020, [REDACTED]

[REDACTED]

[REDACTED]

119. Also in May 2020, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

120. Ultimately, Teva Defendants [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] TEVA-20CV22324-00000914.

121. [REDACTED]

[REDACTED]

[REDACTED]

122. One of the ways NDMA can form is through a reaction of nitrosating agents with amines during the production process, such as a reaction of sodium nitrite with amine in acidic conditions.

123. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

124. [REDACTED]

[REDACTED]

125. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

126. Teva Defendants [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

127. [REDACTED]

[REDACTED] TEVA-20CV234-00000173.

128. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

129. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] TEVA-20CV234-00000173.

130. [REDACTED]

[REDACTED]

[REDACTED]

131. In connection with its recalls, Teva Defendants [REDACTED]

[REDACTED]

132. [REDACTED]

[REDACTED]

133. Prior to the recalls, [REDACTED]

[REDACTED]

[REDACTED]

134. Notably, Teva Defendants also manufactured and sold metformin products made under different ANDA approvals, which [REDACTED]

[REDACTED]

135. Teva Defendants never recalled any metformin products made under its other ANDAs, nor did the FDA ever require such. This, combined with the fact that other manufacturers' metformin products were never recalled, underscores that there ways exist to manufacture metformin products to avoid NDMA contamination, but that Teva Defendants [REDACTED]

[REDACTED]

136. Teva Defendants never re-introduced any MCDs bearing the NDCs 62037-577-01, 62037-577-10, 62037-571-01, and 627037-571-10 for sale in the

United States

[REDACTED]

137.

[REDACTED]

138.

[REDACTED]

139.

[REDACTED]

140. At a minimum, Teva Defendants' inability to assure consumers that NDMA is not present in a particular bottle is itself a deviation from cGMP and renders all at-issue MCDs they made unmerchantable and unfit for use. No

reasonable purchaser would knowingly buy a product for which the manufacturer cannot vouch for the product’s identity, strength, quality, and purity, or certainly would pay a different amount than they did had they known. Indeed, such a product would be considered adulterated or misbranded and illegal to sell given the levels of NDMA detected in all samples tested.

**C. Granules’ and Heritage’s Metformin Was Uniformly Contaminated With NDMA**

*1. Granules’ Metformin Was Uniformly Contaminated With NDMA*

141. Granules’ manufacturing process for MCDs was systemically deficient to such an extent that all of its at-issue MCDs were contaminated with NDMA

142. During the relevant time period, Granules manufactured and sold multiple metformin products.

143. Among these products were metformin ER products made and sold under regulatory approval ANDA209313, which was the approval for both the 500mg and 750mg strength metformin ER products made by Granules.

144. Granules manufactured and sold MCDs during the relevant time period that bore the following with the following NDCs:

<b>NDC</b>	<b>Package Count</b>	<b>ANDA File Number</b>
<b>70010-491-01 (500 mg)</b>	<b>100 count bottles</b>	<b>209313</b>
<b>70010-491-10 (500 mg)</b>	<b>1000 count bottles</b>	<b>209313</b>

<b>NDC</b>	<b>Package Count</b>	<b>ANDA File Number</b>
<b>70010-492-01 (750 mg)</b>	<b>100 count bottles</b>	<b>209313</b>
<b>70010-492-05 (750 mg)</b>	<b>500 count bottles</b>	<b>209313</b>

145. The 750mg products (NDCs 70010-492-01 and 70010-492-05) were identical to each other, and made using the exact same manufacturing process. The only difference between the NDCs for the two 750mg products, was the package size, i.e., either a 100-pill count or a 500-pill count. This is also indicated by the first eight digits of the NDCs being identical except for the last two digits of “01” or “05,” which merely denotes the pill count per bottle.

146. Being subject to the same regulatory approval, ANDA209313, both the 750mg products (NDCs 70010-492-01 and 70010-492-05) and the 500mg product (NDC 70010-491-01, as well as the larger package size for this same product NDC 70010-491-10) were manufactured using the same processes, materials, and conditions.

147. Indeed, [REDACTED]

[REDACTED]

[REDACTED]

*See*

GRANULES\_METFORMIN\_000058152.

148. All of the MCDs with the above-referenced NDCs—NDCs 70010-492-01, 70010-492-05, and NDC 70010-491-01 (as well as NDC 70010-491-10)—were

manufactured through the same process, with the same components (e.g., metformin API, excipients, etc.).

149. The Valisure Citizen’s Petition specifically found NDMA in Granules Defendants’ at-issue MCDs bearing NDC 70010-491-01 contained NDMA.

150. In May 2020, [REDACTED]  
[REDACTED]  
[REDACTED]

151. As noted *supra*, one of the ways NDMA can form is through a reaction of nitrosating agents with amines during the production process, such as a reaction of sodium nitrite with amine in acidic conditions.

152. Per Granules Defendants’ own investigation, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

153. Granules Defendants [REDACTED]  
[REDACTED]

154. On July 3, 2020, Granules announced to the FDA that it was voluntarily recalling twelve (12) lots of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, 100 and 500 count bottles within expiry to the consumer level due to

the detection of N-Nitrosodimethylamine (NDMA) levels above the Acceptable Daily Intake Limit.<sup>35</sup> Granules recall of the 12 distributed lots within expiry of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg from the market consisted of all Metformin sold by Granules at that time.<sup>36</sup> Thus, any purchase of Granules Metformin with NDC codes 70010-492-01 and 70010-492-05 are presumed to be adulterated and contaminated.

155. [REDACTED]

[REDACTED]

156. [REDACTED]

[REDACTED]

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<sup>35</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/granules-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended>.

<sup>36</sup> *Id.*

[REDACTED]

157. In short, [REDACTED]

[REDACTED]

158. [REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

161. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

162. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

163. Prior to the recalls, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

164. [REDACTED]

[REDACTED]

[REDACTED]

165. Yet, [REDACTED]

[REDACTED]

166. Notably, other manufacturers' metformin products were never recalled. This underscores that ways exist to manufacture metformin products to avoid NDMA contamination, but that Granules Defendants [REDACTED]

[REDACTED]

167. After the recalls in 2020, [REDACTED]

[REDACTED]

[REDACTED]

168. [REDACTED]

[REDACTED]

169. [REDACTED]

[REDACTED]

170. [REDACTED]

171. At a minimum, Granules Defendants' inability to assure consumers that NDMA is not present in a particular bottle is itself a deviation from cGMP and renders all at-issue MCDs they made unmerchantable and unfit for use. No reasonable purchaser would knowingly buy a product for which the manufacturer cannot vouch for the product's identity, strength, quality, and purity, or certainly would pay a different amount than they did had they known. Indeed, such a product would be considered adulterated or misbranded and illegal to sell given the levels of NDMA detected in all samples tested.

2. *Heritage's Metformin Was Uniformly Contaminated With NDMA*

172. During the relevant period, Heritage sold multiple metformin IR products, including MCDs bearing the NDCs 23155-102-01 and 23155-102-10 (metformin IR 500 mg) and 23155-103-10 (metformin IR 850mg).

173. Being subject to the same regulatory approval, ANDA090564, both of these products were manufactured using the same processes, materials, and both of these products were manufactured using the same processes, materials, and conditions.

174. Among the components used in the manufacture of MCDs bearing the NDCs 23155-102-01, 23155-102-10, and 23155-103-10 [REDACTED]

[REDACTED]  
[REDACTED].

175. The Valisure Citizen's Petition specifically found NDMA in Heritage's at-issue MCDs bearing NDCs 23155-102-01, 23155-102-10, and 23155-103-10.

176. In response to the Valisure Citizen's Petition [REDACTED]

[REDACTED]  
[REDACTED]

177. [REDACTED]

[REDACTED]  
[REDACTED]

178. [REDACTED]

[REDACTED]  
[REDACTED]

179. As noted *supra*, one of the ways NDMA can form is through a reaction of nitrosating agents with amines during the production process, such as a reaction of sodium nitrite with amine in acidic conditions.

180. [REDACTED]

[REDACTED]

[REDACTED]

181. Heritage did not recall all MCDs bearing MCDs bearing the NDCs 23155-102-01, 23155-102-10, and 23155-103-10, even though Valisure detected NDMA, [REDACTED]

[REDACTED]

182. Prior to the recalls, [REDACTED]

[REDACTED]

183. [REDACTED]

[REDACTED]

[REDACTED]

184. [REDACTED]

[REDACTED]

**IV. THE CONTAMINATED METFORMIN IS NOT WORTH THE FULL PRICE PLAINTIFFS PAID FOR IT**

185. The presence of NDMA in each of Defendants' MCDs renders them worth less than what Plaintiffs paid for them, if they are worth anything at all.

186. *First*, Plaintiffs all bargained for generic Metformin that was properly manufactured, the bioequivalent of brand name Glucophage, and not contaminated with dangerous carcinogens like NDMA. Yet, Plaintiffs received generic Metformin

that was *not* properly manufactured and the bioequivalent of Glucophage because all of Defendants’ generic Metformin was contaminated with dangerous levels of NDMA due to manufacturing issues. Such defective Metformin products are simply not worth as much as properly manufactured Metformin

187. *Second*, the presence of NDMA rendered the generic Metformin adulterated, misbranded, and illegal to sell. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Similarly, Defendants’ failure to comply with current Good Manufacturing Practices—which led to the introduction of NDMA into the MCDs—also rendered the MCDs adulterated, misbranded, and illegal to sell. *Id.*

**V. PLAINTIFFS PAID FOR METFORMIN THAT WAS NOT PROPERLY MANUFACTURED, CONTAMINATED WITH NDMA, AND NOT THE BIOEQUIVALENT OF GLUCOPHAGE<sup>37</sup>**

**A. Plaintiff Brzozowski Paid For Teva Metformin And Granules Metformin That Were Contaminated With NDMA**

188. As set forth below, Plaintiff Brzozowski paid for at least the following Metformin medications that were manufactured by at least the following

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<sup>37</sup> On August 28, 2024, the Court ordered that substantial completion of document productions be concluded by January 16, 2025. ECF No. 475. Nearing this deadline, Plaintiffs anticipated the production of documents which would have disclosed the extent of each defendant’s defective lots (to the extent that any defendant could legitimately contend that their manufacturing processes did not result in uniform contamination of all their MCD), so that plaintiffs could present facts essential to justify their standing. However, only 10 days before the substantial completion date, the Court dismissed the Third Amended Complaint without prejudice and required repleading. ECF No. 517. Thus, Plaintiffs did not have the

Manufacturer Defendants, all of which were sold by Defendant CVS to Plaintiff Brzozowski in New Jersey:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2012.09.21	Metformin HCL ER 500mg tablet	000937-267-01	\$20.59	Teva
2012.12.15	Metformin HCL ER 500mg tablet	000937-267-01	\$20.59	Teva
2019.12.19	Metformin HCL ER 500mg tablet	70010-491-10	\$3.00	Granules
2019.12.31	Metformin HCL ER 500mg tablet	70010-491-10	\$3.00	Granules

189. The Granules Defendants' MCDs bearing NDC 70010-491-10 that Plaintiff Brzozowski purchased were within expiry just as the same MCDs bearing NDC 70010-491-10 that tested and found to contain NDMA as described *supra*. As Plaintiff Brzozowski's purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Granules all-lots recalls of the MCDs within expiry, on information and belief all were contaminated with NDMA and not cGMP-compliant.

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opportunity to review key evidence that would bolster their allegations of standing in this Fourth Amended Complaint. Should the Court determine that the present allegations are not sufficient to establish standing, the Court should once again allow for repleading *after* substantial completion of discovery.

190. By listing these medications as “Metformin,” the Teva, Granules, and CVS Defendants expressly and impliedly warranted to Plaintiff Brzozowski that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

191. Contrary to these representations, Plaintiff Brozowski’s MCDs were *not* properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants’ uniform manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure’s testing and other recalls.

192. But for Defendants’ misrepresentations and omissions, Plaintiff Brzozowski would not have paid as much for the MCDs as he did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Brzozowski would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Brzozowski’s generic MCDs were adulterated, misbranded, and thus, illegally sold.

**B. Plaintiff Hann Paid For Amneal Metformin And Heritage Metformin That Were Contaminated With NDMA**

193. As set forth below, Plaintiff Hann paid for at least the following Metformin medications that were manufactured by at least the following

Manufacturer Defendants, all of which were sold by Walgreens to Plaintiff Hann in California:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2018.01.10	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.02.07	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.03.08	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.04.02	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.05.28	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.05.27	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.06.28	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.07.25	Metformin HCL ER 500mg tablet	65162-0177-10	\$2.20	Amneal
2018.08.18	Metformin HCL ER 850mg tablet	23155-0102-10	\$8.24	Granules/Heritage
2018.11.15	Metformin HCL ER 850mg tablet	23155-0102-10	\$8.24	Granules/Heritage

194. The Heritage Defendants' MCDs bearing NDC bearing NDC 23155-102-05 that Plaintiff Hann purchased were within expiry just as the same MCDs bearing NDC 23155-102-01 (the only difference being package size), that were tested and found to contain NDMA as described *supra*. As Plaintiff Hann's purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Amneal all-lots recalls of the MCDs within expiry as described *supra*, on information and belief all were contaminated with NDMA and not cGMP-compliant.

195. By listing these medications as "Metformin," the Amneal and Granules, Defendants expressly and impliedly warranted to Plaintiff Hann that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

196. Contrary to these representations, Plaintiff Hann's MCDs were not properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants' uniform manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure's testing and other recalls.

197. But for Defendants’ misrepresentations and omissions, Plaintiff Hann would not have paid as much for the MCDs as he did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Hann would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Hann’s generic MCDs were adulterated, misbranded, and thus, illegally sold.

**C. Plaintiff Harris Paid For Granules Metformin That Was Contaminated With NDMA**

198. As set forth below, Plaintiff Harris paid for at least the following Metformin medications that were manufactured by at least the following Manufacturer Defendants, all of which were sold by Rite Aid to Plaintiff Harris in New Jersey:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2017.05.27	Metformin HCL ER 500mg tablet	23155-102-05	\$0.00	Granules/Heritage
2020.01.14	Metformin HCL ER 500mg tablet	70010-0491-01	\$1.30	Granules
2020.04.22	Metformin HCL ER 500mg tablet	70010-0491-01	\$1.30	Granules
2020.07.22	Metformin HCL ER 500mg tablet	70010-0491-01	\$1.30	Granules
2020.10.21	Metformin HCL ER 500mg tablet	70010-0491-01	\$1.30	Granules

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2021.01.19	Metformin HCL ER 500mg tablet	70010-0491-01	\$1.30	Granules

199. The Granules Defendants’ MCDs bearing NDC 70010-491-01 and Heritage Defendants’ MCDs bearing NDC 23155-102-05 that Plaintiff Harris purchased were within expiry just as the same MCDs bearing NDC 70010-491-10 that were tested and found to contain NDMA as described *supra*, and the MCDs bearing NDC 23155-102-05 that Plaintiff Harris purchased were within expiry just as the same MCDs bearing NDC 23155-102-01 (the only difference being package size), that were tested and found to contain NDMA as described *supra*. As Plaintiff Harris’s purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra*, on information and belief all were contaminated with NDMA and not cGMP-compliant.

200. By listing these medications as “Metformin,” the Granules Defendants expressly and impliedly warranted to Plaintiff Harris that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

201. Contrary to these representations, Plaintiff Harris’s MCDs were not properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants’ uniform

manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure’s testing and other recalls.

202. But for Defendants’ misrepresentations and omissions, Plaintiff Harris would not have paid as much for the MCDs as she did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Harris would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Harris’s generic MCDs were adulterated, misbranded, and thus, illegally sold.

**D. Plaintiff Wineinger Paid For Granules Metformin That Was Contaminated With NDMA**

203. As set forth below, Plaintiff Wineinger paid for at least the following Metformin medications that were manufactured by at least the following Manufacturer Defendants, all of which were sold by Defendant Walmart to Plaintiff Wineinger in Indiana:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2020.03.02	Metformin HCL ER 500mg tablet	23155-0102-10	\$9.08	Granules/Heritage
2021.03.03	Metformin HCL ER 500mg tablet	70010-0063-10	\$45.22	Granules/Heritage

204. The Heritage Defendants' MCDs bearing NDC bearing NDC 23155-102-01 that Plaintiff Wineinger purchased were within expiry just as the same MCDs bearing NDC 23155-102-01 (the only difference being package size), that were tested and found to contain NDMA as described *supra*.

205. By listing these medications as "Metformin," the Granules and Walmart Defendants expressly and impliedly warranted to Plaintiff Wineinger that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

206. Contrary to these representations, Plaintiff Wineinger's MCDs were not properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants' uniform manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure's testing and other recalls.

207. But for Defendants' misrepresentations and omissions, Plaintiff Wineinger would not have paid as much for the MCDs as she did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Wineinger would not have been able to purchase the generic MCDs in the first place because, due to the NDMA

contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Wineinger’s generic MCDs were adulterated, misbranded, and thus, illegally sold.

**E. Plaintiff Hendrix Paid For Amneal (Relabeled as AvKare) Metformin That Was Contaminated With NDMA**

208. As set forth below, Plaintiff Hendrix paid for at least the following Metformin medications that were manufactured by at least the following Manufacturer Defendants, all of which were sold by Express Scripts to Plaintiff Hendrix in California:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2018.02.08	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2018.05.08	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2018.08.10	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2018.11.02	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2019.01.28	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2019.04.13	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2019.07.07	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2019.10.01	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2019.12.13	Metformin HCL ER 500mg tablet	42291-610-10	\$7.00	Amneal (relabeled as AvKare)
2020.03.29	Metformin HCL ER 500mg tablet	42291-610-10	\$10.00	Amneal (relabeled as AvKare)
2020.06.27	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2020.09.25	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2020.12.06	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2021.03.06	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2021.06.04	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2021.09.05	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2021.12.04	Metformin HCL ER 500mg tablet	70010-491-05	\$10.00	Granules
2022.03.04	Metformin HCL ER 500mg tablet	70010-491-05	\$12.00	Granules
2022.06.02	Metformin HCL ER 500mg tablet	70010-491-05	\$12.00	Granules

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
2022.08.31	Metformin HCL ER 500m tablet	70010-491-05	\$12.00	Granules

209. The Granules Defendants’ MCDs bearing NDC bearing NDC 70010-0491-05 that Plaintiff Hendrix purchased were within expiry just as the same MCDs bearing NDC 70010-0491-01 (the only difference being package size), that were tested and found to contain NDMA as described *supra*. The Amneal-manufactured MCDs bearing NDC 42291-610-10 that Plaintiff Hendrix purchased were within expiry just as the same MCDs bearing the corresponding 500mg NDC for Amneal discussed *supra*, all of which were recalled and/or contained NDMA, because on information and belief AvKare simply relabeled and repackaged the same Amneal product which was entirely recalled by Amneal, and which AvKare also recalled. Plaintiff Hendrix’s purchases of NDC 42291-610-10 were all within expiry and, given the Amneal and AvKare all-lots recalls of the MCDs within expiry, on information and belief all were contaminated with NDMA and not cGMP-compliant.

210. By listing these medications as “Metformin,” the Amneal Defendants and Granules Defendants expressly and impliedly warranted to Plaintiff Hendrix that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

211. Contrary to these representations, Plaintiff Hendrix's MCDs were not properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants' uniform manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure's testing and other recalls.

212. But for Defendants' misrepresentations and omissions, Plaintiff Hendrix would not have paid as much for the MCDs as he did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Hendrix would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Hendrix's generic MCDs were adulterated, misbranded, and thus, illegally sold.

**F. Plaintiff Brice Paid For Amneal Metformin That Was Contaminated With NDMA**

213. As set forth below, Plaintiff Brice paid for at least the following Metformin medications that were manufactured by at least the following Manufacturer Defendants, all of which were sold by Wal-Mart to Plaintiff Brice in Florida:

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
01/15/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
02/12/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
03/13/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
04/16/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
05/14/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
06/10/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
07/11/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
08/08/2018	Metformin ER 500 Mg	53746-0178-01	\$3.82	Amneal
09/06/2018	Metformin ER 500 Mg	53746-0178-01	\$3.90	Amneal
10/12/2018	Metformin ER 500 Mg	53746-0178-01	\$3.90	Amneal
11/08/2018	Metformin ER 500 Mg	53746-0178-01	\$3.90	Amneal
12/10/2018	Metformin ER 500 Mg	53746-0178-01	\$3.90	Amneal

Date	Strength & Formulation	NDC	Patient Paid Amount	Manufacturer
01/06/2019	Metformin ER 500 Mg	53746-0178-01	\$4.00	Amneal
02/07/2019	Metformin ER 500 Mg	53746-0178-01	\$6.00	Amneal
01/17/2020	Metformin HCL ER 500 Mg	65162-0178-10	\$6.00	Amneal
03/25/2020	Metformin HCL ER 500 Mg	65162-0178-10	\$6.00	Amneal
05/28/2020	Metformin HCL ER 500 Mg	65162-0178-10	\$4.00	Amneal

214. The Amneal Defendants’ MCDs bearing NDC 53746-0178-01 or 65162-1078-10 that Plaintiff Brice purchased were within expiry just as the same MCDs bearing the same NDCS that were tested and found to contain NDMA as described *supra*. As Plaintiff Brice’s purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Amneal all-lots recalls of the MCDs within expiry, on information and belief all were contaminated with NDMA and not cGMP-compliant.

215. By listing these medications as “Metformin,” the Amneal Defendants expressly and impliedly warranted to Plaintiff Brice that their generic MCDs were the same as brand-name Glucophage, were properly manufactured, and were free from carcinogenic impurities like NDMA.

216. Contrary to these representations, Plaintiff Brice's MCDs were not properly manufactured, were all contaminated with NDMA, and were not the same as brand-name Glucophage as a result. This is so because (i) Defendants' uniform manufacturing practices rendered all of their MCDs defective and contaminated with NDMA, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the time of Valisure's testing and other recalls.

217. But for Defendants' misrepresentations and omissions, Plaintiff Hendrix would not have paid as much for the MCDs as he did, or would not have paid anything for the MCDs at all. Indeed, Plaintiff Brice would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Plaintiff Brice's generic MCDs were adulterated, misbranded, and thus, illegally sold.

**G. Plaintiff MSPRC's Assignors Paid For Amneal, Teva, Granules/Heritage, and Amneal (Relabeled as AvKare) Metformin That Was Contaminated With NDMA**

218. MSPRC's limited liability company agreement provides for the establishment of one or more specific series. All records of all series are maintained together with all assets of MSPRC.

219. Certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Master Class Complaint to Series LLCs of

MSPRC. Pursuant to MSPRC's limited liability agreement, all rights arising from the assignment to its series (including the assignments discussed below), along with the right to bring any lawsuit in connection with that assignment (including those below), belong to MSPRC. As such, MSPRC has the right and power to sue defendants to recover the payments at issue in this action.

220. 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:

221. 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 provide 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.

222. 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 provides the following language:

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

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

[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].

224. Summacare 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.

225. 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 provides the following language:

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

may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

226. Defendants have manufactured and distributed MCDs containing NDMA throughout the United States, for which plaintiff consumers made co-payments and TPPs, like MSPRC's assignors, paid. MSPRC's assignors made payments for Defendants' NDMA-containing Metformin drugs in one or more of the following states or territories: Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, the District of Columbia, and Puerto Rico. MSPRC's assignors' payments include those payments for Defendants' contaminated MCDs, which were also manufactured, distributed, and sold during the relevant period.

227. MSPRC has identified over 19,000 claim lines relating to payments that MSPRC's assignors, ConnectiCare, Emblem, and SummaCare made for the purchase of Defendant Amneal's MCDs with NDC codes 53746-178-01, 53746-178-90, 65162-178-10, and 65162-179-10 that have all been shown to contain

NDMA above the daily acceptable limit. Below is a sample of the payments that MSPRC's assignors made for the purchase of Defendant Amneal's NDMA-contaminated MCDs<sup>38</sup>:

mSP_mrd_id	mSP_client	mSP_member_id_updated	mSP_dos	mSP_paid_amount_value	mSP_ndc	manufacturer name
20532172	CONC-CONC	17512395-CONC-CONC	2015-03-24	\$13.26	53746017801	AMNEAL
1543671	CONC-CONC	M2058907501-CONC-CONC	2016-08-10	\$5.25	53746017801	AMNEAL
19487890	CONC-CONC	18155785-CONC-CONC	2014-06-27	\$1.25	53746017801	AMNEAL
14502778	CONC-CONC	17985204-CONC-CONC	2012-01-23	\$1.25	53746017801	AMNEAL
15097141	CONC-CONC	18127799-CONC-CONC	2012-09-09	\$96.57	53746017801	AMNEAL
29122690	EHTH-EHTH	24322225001-EHTH-EHTH	2013-03-22	\$3.99	53746017801	AMNEAL
36481709	EHTH-EHTH	09170877601-EHTH-EHTH	2015-09-14	\$18.68	53746017801	AMNEAL
35721133	EHTH-EHTH	05234409301-EHTH-EHTH	2015-01-01	\$19.53	53746017801	AMNEAL
172515410	EHTH-EHTH	05636147701-EHTH-EHTH	2017-07-05	\$15.00	53746017801	AMNEAL
68564639	EHTH-EHTH	22034966701-EHTH-EHTH	2014-08-04	\$30.17	53746017801	AMNEAL
5367734	SMCR-SMCR	A0031538000-SMCR-SMCR	2013-10-10	\$30.25	53746017801	AMNEAL
25058874	SMCR-SMCR	A0022583600-SMCR-SMCR	2010-03-09	\$5.00	53746017801	AMNEAL
67205888	SMCR-SMCR	A0045830900-SMCR-SMCR	2019-02-02	\$6.00	53746017801	AMNEAL
7308398	SMCR-SMCR	A0041567500-SMCR-SMCR	2014-12-11	\$6.23	53746017801	AMNEAL
25361177	SMCR-SMCR	A0032277900-SMCR-SMCR	2011-07-21	\$1.50	53746017801	AMNEAL

<sup>38</sup> Plaintiff MSPRC has previously produced to the Defendant Manufacturers a complete list of its assignors' purchases by NDC for each of the alleged NDMA-contaminated MCDs. In total, MSPRC's assignors have paid for the Defendant Manufacturers' contaminated MCDs that were prescribed to over 29,000 members enrolled in one of their health plans.

228. All of the above representative NDC purchases within expiry just as the same MCDs bearing the same NDCs that were tested and found to contain NDMA as described supra. As MSP's purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Amneal all-lots recalls of the MCDs within expiry, on information and belief all were contaminated with NDMA and not cGMP-compliant.

229. All of the above representative NDC purchases were within the same as the MCDs tested and found to contain NDMA as described *supra*

230. MSPRC has identified over 1,700 claim lines relating to payments that MSPRC's assignors, ConnectiCare, Emblem, and SummaCare made for the purchase of Defendant Teva/Actavis' MCDs with NDC codes 62037-571-01 and 62037-571-10 that have all been shown to contain NDMA above the daily acceptable limit. Below is a sample of the payments that MSPRC's assignors made for the purchase of Defendant Teva/Actavis' NDMA-contaminated MCDs:

msp_mrd_id	msp_client	msp_member_id_updated	msp_dos	msp_paid_amount_value	msp_ndc	manufacturer name
15350126	CONC-CONC	18196709-CONC-CONC	2012-12-07	\$8.25	6203705710 1	ACTAVIS PHARMA
15063159	CONC-CONC	18024707-CONC-CONC	2012-08-27	\$8.21	6203705710 1	ACTAVIS PHARMA
14575926	CONC-CONC	18024707-CONC-CONC	2012-02-21	\$6.10	6203705710 1	ACTAVIS PHARMA
15250690	CONC-CONC	18024707-CONC-CONC	2012-11-02	\$9.02	6203705710 1	ACTAVIS PHARMA
14305697	CONC-CONC	18028444-CONC-CONC	2011-10-31	\$14.87	6203705710 1	ACTAVIS PHARMA

msp_mrd_id	msp_client	msp_member_id_updated	msp_dos	msp_paid_amount_value	msp_ndc	manufacturer name
153922194	EHTH-EHTH	10148206701-EHTH-EHTH	2012-02-19	\$25.47	62037057101	ACTAVIS PHARMA
153921781	EHTH-EHTH	10148206701-EHTH-EHTH	2012-11-18	\$34.90	62037057101	ACTAVIS PHARMA
31291264	EHTH-EHTH	10148206701-EHTH-EHTH	2013-10-08	\$26.77	62037057101	ACTAVIS PHARMA
153927129	EHTH-EHTH	10148206701-EHTH-EHTH	2012-09-13	\$33.31	62037057101	ACTAVIS PHARMA
153921783	EHTH-EHTH	10148206701-EHTH-EHTH	2012-01-19	\$25.94	62037057101	ACTAVIS PHARMA
26124018	SMCR-SMCR	A0041839300-SMCR-SMCR	2011-06-01	\$2.55	62037057101	ACTAVIS PHARMA
25960840	SMCR-SMCR	A0041839300-SMCR-SMCR	2011-03-31	\$2.55	62037057101	ACTAVIS PHARMA
24701946	SMCR-SMCR	A0032136600-SMCR-SMCR	2009-12-16	\$31.32	62037057101	ACTAVIS PHARMA
5425090	SMCR-SMCR	A0044943200-SMCR-SMCR	2013-11-15	\$3.84	62037057101	ACTAVIS PHARMA
67208542	SMCR-SMCR	A9000400700-SMCR-SMCR	2019-02-03	\$20.88	62037057101	ACTAVIS PHARMA

231. All of the above representative NDC purchases within expiry just as the same MCDs bearing the same NDCs that were tested and found to contain NDMA as described supra. As MSP's purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described supra and, given the Teva recalls of all MCDs with these NDCs within expiry, on information and belief all were contaminated with NDMA and not cGMP-compliant.

232. MSPRC has identified over 19,000 claim lines relating to payments that MSPRC's assignors, ConnectiCare, Emblem, and SummaCare made for the purchase of Defendant Granules/Heritage's MCDs with NDC codes 70010-491-01, 23155-102-01, and 23155-103-10 and that have all been shown to contain NDMA

above the daily acceptable limit. Below is a sample of the payments that MSPRC’s assignors made for the purchase of Defendant Granules/Heritage’s NDMA-contaminated MCDs:

msp_mrd_id	msp_client	msp_member_id_updated	msp_dos	msp_paid_amount_value	msp_ndc	manufacturer name
296522	CONC-CONC	17452840-CONC-CONC	2015-10-06	\$2.85	23155010310	HERITAGE
1299996	CONC-CONC	M1812636601-CONC-CONC	2016-06-08	\$1.26	23155010201	HERITAGE
1706544	CONC-CONC	M1752924901-CONC-CONC	2016-09-21	\$11.82	23155010201	HERITAGE
19905149	CONC-CONC	20517037-CONC-CONC	2014-10-18	\$1.50	23155010310	HERITAGE
1357578	CONC-CONC	M1828309301-CONC-CONC	2016-06-23	\$10.31	23155010201	HERITAGE
198136075	EHTH-EHTH	K9053352801-EHTH-EHTH	2023-08-14	\$6.70	70010049101	GRANULES
198272158	EHTH-EHTH	R0000031888-EHTH-EHTH	2024-06-17	\$35.86	70010049101	GRANULES
194522394	EHTH-EHTH	K4003615301-EHTH-EHTH	2019-10-25	\$13.92	70010049101	GRANULES
35353675	EHTH-EHTH	08052597001-EHTH-EHTH	2017-01-30	\$7.55	23155010201	HERITAGE
37122179	EHTH-EHTH	08052597001-EHTH-EHTH	2017-01-30	\$7.31	23155010201	HERITAGE
171627652	EHTH-EHTH	08052597001-EHTH-EHTH	2017-06-09	\$5.88	23155010201	HERITAGE
114737066	SMCR-SMCR	A0050771300-SMCR-SMCR	2022-10-29	\$1.45	70010049101	GRANULES
80668074	SMCR-SMCR	A9000100800-SMCR-SMCR	2020-06-17	\$4.50	70010049101	GRANULES
110498047	SMCR-SMCR	A0055905700-SMCR-SMCR	2022-09-08	\$3.60	70010049101	GRANULES
80326371	SMCR-SMCR	A9000856700-SMCR-SMCR	2020-05-14	\$10.86	23155010310	HERITAGE
83868967	SMCR-SMCR	A9001125200-SMCR-SMCR	2020-09-10	\$10.40	70010049101	GRANULES

233. Because, as alleged above, all of Defendants’ MCDs are contaminated with NDMA, all of the MCDs that MSPRC paid for were contaminated with NDMA

and not worth the full price that MSPRC paid for them. Had Defendants not misrepresented or otherwise omitted that their MCDs were not properly manufactured, contaminated with NDMA, and not the bioequivalent of Glucophage, MSPRC would not have paid as much for these MCDs as they did, if they would have paid anything at all. Indeed, MSPRC could not have purchased these MCDs because the presence of NDMA renders these MCDs adulterated, misbranded, and illegal to sell.

**H. Plaintiff County Of Monmouth Paid For Metformin That Was Contaminated With NDMA**

234. County of Monmouth, by and through its appointed administrator, manages operations of sixty county departments comprised of more than 2,700 employees to deliver services to residents. County of Monmouth also operates a self-funded health insurance plan and workers' compensation plan for its employees and retirees and directly pays for all or a portion of its insureds' (including employees and dependents) healthcare costs, including but not limited to prescription costs.

235. County of Monmouth's Human Resources Benefits Division administers the County's self-funded employee benefit programs and employee enrollments. The programs include medical and prescription drug benefits to participants along with their dependents and retirees (collectively, "beneficiaries").

236. County of Monmouth's administers its health and welfare fund in New Jersey and its beneficiaries purchased MCDs and County of Monmouth paid for

MCDs from the Manufacturer Defendants and Pharmacy Defendants in, *inter alia*, New Jersey, South Carolina, and Florida. Beneficiaries of County of Monmouth purchased MCDs during the Class Period for personal use. County of Monmouth is ultimately at risk and responsible for reimbursing or paying for beneficiaries' purchases of prescription drugs. County of Monmouth paid more for MCDs than it would have absent Defendants' misconduct.

237. Defendants expressly and impliedly warranted to County of Monmouth (either directly, or indirectly by adopting warranties that were passed along to and incorporated by another Defendant further downstream and mentioned in this paragraph) that their respective MCDs were the same as the branded RLD, not contaminated with any carcinogenic impurities, and were made in a cGMP-complaint manner. But in fact, County of Monmouth reimbursed or paid for a product for its beneficiaries that was not the same as the RLD because the generic MCD was contaminated with NDMA over interim limits, as confirmed by the March 2, 2020 Valisure petition that detected the presence of NDMA in generic MCDs. Further, the MCDs reimbursed or paid for by County of Monmouth, as described herein, were not the same as the RLDs not only because they were contaminated with NDMA, but also because they were not made in a cGMP-compliant manner (*e.g.*, not made with adequate quality assurances that the product was free from nitrosamine contamination).

238. Had County of Monmouth known the product it purchased was not the same as the RLD because it was contaminated with NDMA and was not made in a cGMP-compliant manner, County of Monmouth would not have reimbursed or paid for these Defendants' MCDs for its beneficiaries. Indeed, County of Monmouth would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, County of Monmouth's generic MCDs were adulterated, misbranded, and thus, worthless and illegally sold. Likewise, had Defendants' deception about the impurities within their products and deficient manufacturing practices of their products been made known earlier, County of Monmouth would not have reimbursed or paid for these Defendants' MCDs for its beneficiaries.

239. For example, and only to further demonstrate standing, County of Monmouth alleges some exemplar payments for the MCDs in the table below. In each instance, County of Monmouth received a request to reimburse a prescription drug on behalf of an enrollee. County of Monmouth paid the amounts indicated for contaminated, non-cGMP compliant, FDA-recalled lots of MCDs. To be clear, the table below does not demonstrate all of County of Monmouth's payments for MCDs, let alone all of the County of Monmouth's damages.

<b>Defendant</b>	<b>NDC</b>	<b>Label Name</b>
Heritage	23155010201*	METFORMIN HCL 500 MG TABLET
Heritage	23155010310*	METFORMIN HCL 850 MG TABLET
Amneal	53746017801^	METFORMIN HCL ER 500 MG TABLET

Amneal	53746017805^	METFORMIN HCL ER 500 MG TABLET
Amneal	53746017810^	METFORMIN HCL ER 500 MG TABLET
Amneal	53746017901^	METFORMIN HCL ER 750 MG TABLET
Actavis (Teva)	62037057110^	METFORMIN HCL ER 500 MG TABLET
Amneal	65162017810^	METFORMIN HCL ER 500 MG TABLET
Amneal	65162017850^	METFORMIN HCL ER 500 MG TABLET
Amneal	65162017910^	METFORMIN HCL ER 750 MG TABLET
Granules	70010049101*	METFORMIN HCL ER 500 MG TABLET
Granules	70010049201^	METFORMIN HCL ER 750 MG TABLET

\* = NDMA found by Valisure

^ = all lots recalled

240. All of the above representative NDC purchases within expiry just as the same MCDs bearing the same NDCs that were tested and found to contain NDMA as described *supra*. As County of Monmouth's purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Amneal, Actavis (Teva), and Granules recalls of all MCDs with the corresponding NDCs within expiry as described *supra*, on information and belief all were contaminated with NDMA and not cGMP-compliant.

241. Because, as alleged above, all of Defendants' MCDs are contaminated with NDMA, all of the MCDs that County of Monmouth paid for were contaminated with NDMA and not worth the full price that County of Monmouth paid for them. Had Defendants not misrepresented or otherwise omitted that their MCDs were not properly manufactured, contaminated with NDMA, and not the bioequivalent of Glucophage, County of Monmouth would not have paid as much for these MCDs as

they did, if they would have paid anything at all. Indeed, County of Monmouth could not have purchased these MCDs because the presence of NDMA renders these MCDs adulterated, misbranded, and illegal to sell.

**I. Plaintiff Ohio Carpenters Paid For Metformin That Was Contaminated With NDMA**

242. Ohio Carpenters' provides healthcare benefits to Participants and their eligible dependents (collectively, "beneficiaries"). Ohio Carpenters' insured beneficiaries are located throughout the United States. Plaintiff is a self-funded health insurance plan and workers' compensation plan for its employees and retirees and directly pays for all or a portion of its insureds' (including employees and dependents) healthcare costs, including, but not limited to, prescription costs.

243. Ohio Carpenters administers its health and welfare fund in Michigan and its beneficiaries purchased MCDs and Ohio Carpenters paid for MDCs from the Manufacturer Defendants and Pharmacy Defendants in, *inter alia*, Florida, Georgia, Indiana, Kentucky, Michigan, North Carolina, Ohio and West Virginia. Beneficiaries of Ohio Carpenters purchased MCDs during the Class Period for personal use. Ohio Carpenters is ultimately at risk and responsible for reimbursing or paying for a portion of beneficiaries' purchases of prescription drugs. Ohio Carpenters paid more for MCDs than it would have absent Defendants' misconduct.

244. Defendants expressly and impliedly warranted to Ohio Carpenters (either directly, or indirectly by adopting warranties that were passed along to and

incorporated by another Defendant further downstream and mentioned in this paragraph) that their respective MCDs were the same as the branded RLD, not contaminated with any carcinogenic impurities, and were made in a cGMP-complaint manner. But in fact, Ohio Carpenters reimbursed or paid for a product for its beneficiaries that was not the same as the RLD because the generic MCD was contaminated with NDMA over the interim limit, as confirmed by the March 2, 2020 Valisure petition that detected the presence of NDMA in generic MCDs.

245. Further, the MCDs reimbursed or paid for by Ohio Carpenter, as described herein, were not the same as the RLDs not only because they were contaminated with NDMA, but also because they were not made in a cGMP-compliant manner (*e.g.*, not made with adequate quality assurances that the product was free from nitrosamine contamination). Had Ohio Carpenters known the product it purchased was not the same as the RLD because it was contaminated with NDMA and was not made in a cGMP-compliant manner, Ohio Carpenters would not have reimbursed or paid for these Defendants' MCDs for its beneficiaries. Indeed, Ohio Carpenters would not have been able to purchase the generic MCDs in the first place because, due to the NDMA contamination and non-cGMP compliant manufacture of these MCDs, Ohio Carpenters generic MCDs were adulterated, misbranded, and thus, worthless and illegally sold. Likewise, had Defendants' deception about the impurities within their products and deficient manufacturing practices of their

products been made known earlier, Ohio Carpenters would not have reimbursed or paid for these Defendants' MCDs for its beneficiaries.

246. For example, and only to further demonstrate standing, Ohio Carpenters alleges some exemplar payments for the MCDs in the table below. In each instance, Ohio Carpenters received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service indicated below. Ohio Carpenters paid the amounts indicated for contaminated, non-cGMP compliant, FDA-recalled lots of MCDs. To be clear, the table below does not demonstrate all of Ohio Carpenters' payments for MCDs, let alone all the Ohio Carpenters' damages.

<b>Defendant</b>	<b>NDC Code</b>	<b>LABEL NAME</b>
Amneal	53746017901^	METFORMIN HCL ER 750 MG TABLET
Amneal	53746017805^	METFORMIN HCL ER 500 MG TABLET
Amneal	53746017810^	METFORMIN HCL ER 500 MG TABLET
Amneal	53746017805^	METFORMIN HCL ER 500 MG TABLET

\* = NDMA found by Valisure

^ = recalled

247. All of the above representative NDC purchases within expiry just as the same MCDs bearing the same NDCs that were tested and found to contain NDMA as described *supra*. As Ohio Carpenters' purchases of these NDCs were all within expiry the same as the MCDs tested and found to contain NDMA as described *supra* and, given the Amneal recalls of all MCDs with the corresponding NDCs within

expiry as described *supra*, on information and belief all were contaminated with NDMA and not cGMP-compliant.

248. Because, as alleged above, all of Defendants' MCDs are contaminated with NDMA, all of the MCDs that Ohio Carpenters paid for were contaminated with NDMA and not worth the full price that Ohio Carpenters paid for them. Had Defendants not misrepresented or otherwise omitted that their MCDs were not properly manufactured, contaminated with NDMA, and not the bioequivalent of Glucophage, Ohio Carpenters would not have paid as much for these MCDs as they did, if they would have paid anything at all. Indeed, Ohio Carpenters could not have purchased these MCDs because the presence of NDMA renders these MCDs adulterated, misbranded, and illegal to sell.

### **CLASS ACTION ALLEGATIONS**

249. Plaintiffs seek to represent a Nationwide Class pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) as defined below:

All individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.

250. The Nationwide Class has two sub-classes:

All consumers in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or

household use) that was manufactured, distributed, or sold by any Defendant.

All TPPs in the United States and its territories and possessions that paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Manufacturer, or Wholesaler Defendant.

251. Plaintiffs allege additional sub-classes for all individuals and TPPs in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment – who, paid any amount of money out of pocket for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant (collectively, the “Subclasses”). These include but are not limited to the following:

- (a) Plaintiffs Brzozowski and Harris seek to represent a New Jersey sub-class and/or subclass(es) of states with similar applicable laws to New Jersey.
- (b) Plaintiff Wineinger seeks to represent an Indiana sub-class and/or subclass(es) of states with similar applicable laws to Indiana.
- (c) Plaintiffs Hann and Hendrix seek to represent a California sub-class and/or sub-classes of states with similar applicable laws to California.

252. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the “Class.”

253. 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.

254. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

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

256. **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.

257. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Subclass Members and predominate over any questions affecting an individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

- (a) Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding their generic MCDs;

- (b) Whether each Defendants' MCDs were contaminated with NDMA and not manufactured in compliance with cGMPs, and were thus not identical to the RLDs;
- (c) Whether each Defendant falsely claimed that its MCDs were the same as their RLDs and thus therapeutically interchangeable;
- (d) Whether each Defendant misrepresented or omitted facts regarding its compliance with cGMPs; and
- (e) Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages.

258. **Typicality:** Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs 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 the claims of all other Class Members.

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

260. 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.

261. **Superiority:** A class action is superior to all other available means for the fair and efficient adjudication of this 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 would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' 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.

## **CAUSES OF ACTION**

### **FIRST COUNT**

#### **BREACH OF EXPRESS WARRANTIES – CONSUMER CLASS**

262. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

263. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except Pharmacy Defendants.

264. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs 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, were not contaminated with carcinogenic impurities like NDMA, and were made in a cGMP-compliant manner. 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 Plaintiffs and the members of the Class and Defendants.

265. Each Defendant expressly warranted that its MCDs were fit for its ordinary use 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, were not contaminated with carcinogenic impurities, and were made in a cGMP-compliant manner.

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

267. 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.

268. 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.

269. 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.

270. 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.

271. Plaintiffs and each member of the Class would not have purchased the MCDs had they known these drugs were not the same as the RLD because they were contaminated with NDMA, did not contain the same ingredients as the RLDs because of the NDMA contamination, did not have the same safety and efficacy

profile of the RLD because of the NDMA contamination, and were not made in a cGMP-compliant manner.

272. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs 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.

273. To the extent pre-suit notice was required, Plaintiffs provided same. This includes Plaintiff Brice, whose claim was dismissed without prejudice and she provided pre-suit notice thereafter in accordance with Florida law.

**SECOND COUNT**  
**BREACH OF EXPRESS WARRANTIES – TPP CLASS**

274. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

275. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

276. Each Defendant expressly warranted that its MCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with their RLDs and not contaminated with carcinogenic

impurities. In other words, Defendants expressly warranted that their products were the same as their RLDs, not contaminated with carcinogenic impurities, and were made in a cGMP-compliant manner.

277. Each Defendant sold MCDs that they expressly warranted were the same as the RLDs, compliant with cGMP, not adulterated and/or misbranded, and/or not contaminated with carcinogenic impurities.

278. 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.

279. 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.

280. 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 not contaminated with carcinogenic impurities, 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.

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

282. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

283. To the extent pre-suit notice was required, Plaintiffs provided same.

**THIRD COUNT**  
**BREACH OF IMPLIED WARRANTY – CONSUMER CLASS**

284. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

285. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except not under California, Indiana, or New York law against Pharmacy Defendants.

286. 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 (except not as to New York law against manufacturer defendants): 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.

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

288. Each Defendant's MCDs constituted "goods" or the equivalent within the meaning of the above statutes.

289. Each Defendant was obligated to provide Plaintiffs 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.

290. 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.

291. 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.

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

293. The MCDs were not altered by Plaintiffs or Class members.

294. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs 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.

295. To the extent pre-suit notice was required, Plaintiff provided same. This includes Plaintiff Brice, whose claim was dismissed without prejudice and she provided pre-suit notice thereafter in accordance with Florida law.

**FOURTH COUNT**  
**BREACH OF IMPLIED WARRANTY – TPP CLASS**

296. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

297. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

298. 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 (except not as to New York law against manufacturer defendants): 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.

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

300. Each Defendant's MCDs constituted "goods" or the equivalent within the meaning of the above statutes.

301. Each Defendant was obligated to provide Plaintiffs 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.

302. 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 same was of merchantable quality and fit for that purpose.

303. 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.

304. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' MCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

305. To the extent pre-suit notice was required, Plaintiff provided same.

**FIFTH COUNT**  
**FRAUD – CONSUMER CLASS**

306. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

307. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except Pharmacy Defendants.

308. Defendants affirmatively misrepresented material facts including, inter alia, that their MCDs were therapeutically equivalent to their RLDs as not contaminated with carcinogenic impurities, complied with cGMPs, and/or were not adulterated and/or misbranded.

309. Defendants omitted material facts including, inter alia, that their MCDs were not therapeutically equivalent to their RLDs because of the NDMA contamination, did not comply with cGMPs, and/or were adulterated, misbranded, and/or unapproved as a result of the NDMA contamination.

310. 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 because of the NDMA contamination, did not comply with cGMPs, and/or were adulterated and/or misbranded as a result of the NDMA contamination. 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.

311. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

312. Defendant knowingly, or at least recklessly, represented that its MCDs were manufactured in a cGMP manner and that its MCDs were what they were supposed to be, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls

313. Each Defendant had direct knowledge of the risks of NDMA contamination at least as early as 2018 (if not sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, these and other Defendants knew, and certainly should have known, of the possibility of NDMA creation in their MCDs, particularly because regulators including the FDA issued guidance in the second-half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just

like those used by Defendants to make their MCDs. Yet, each Defendant sat by idly and did nothing until the MCD recalls began in 2020.

314. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that NDMA contamination occurred in MCDs potentially due to the same route of contamination that resulted in NDMA contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started nearly two years before Defendants' recalls of their MCDs.

315. Thus, prior to initiating recalls of MCDs in the United States, each Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But, each Defendant intentionally or recklessly disregarded that knowledge in making its representations that were false or deceptive about their respective MCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a non-cGMP compliant manner, either of which rendered the MCDs adulterated and misbranded.

316. 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.

317. 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.

318. Defendants' misrepresentations and omissions were material.

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

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

321. But for these misrepresentations and omissions, Plaintiffs and other Class Members would not have paid for Defendants' MCDs. Nor could they have, because the MCDs were adulterated, misbranded, and illegally sold.

322. 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. Nor could they have, because the MCDs were adulterated, misbranded, and illegally sold. To the extent applicable, reliance may be presumed in these circumstances.

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

**SIXTH COUNT**  
**FRAUD – TPP CLASS**

324. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

325. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

326. Defendants affirmatively misrepresented material facts including, inter alia, that their MCDs were therapeutically equivalent to their RLDs and did not contain carcinogenic impurities, complied with cGMPs, and/or were not adulterated and/or misbranded.

327. Defendants omitted material facts including, inter alia, that their MCDs were not therapeutically equivalent to their RLDs because they were contaminated with NDMA, did not comply with cGMPs, and/or were adulterated, misbranded, and/or unapproved as a result of the NDMA contamination.

328. Defendants' actions had the effect of fraudulently inducing customers and TPPs to pay in whole or in part for Defendants' MCDs – product which Defendants knew or should have known was not therapeutically equivalent to their RLDs because they were contaminated with NDMA, did not comply with GMPs, and/or were adulterated and misbranded because they were contaminated with NDMA. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for 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.

329. 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.

330. 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.

331. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine

potential in the event of cGMP deviations or failures concerning quality control and risk management.

332. Defendant knowingly, or at least recklessly, represented that its MCDs were manufactured in a cGMP manner and that its MCDs were what they were supposed to be, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

333. Each Defendant had direct knowledge of the risks of NDMA contamination at least as early as 2018 (if not sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, these and other Defendants knew, and certainly should have known, of the possibility of NDMA creation in their MCDs, particularly because regulators including the FDA issued guidance in the second-half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendants to make their MCDs. Yet, each Defendant sat by idly and did nothing until the MCD recalls began in 2020.

334. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that NDMA contamination occurred in MCDs potentially due to the same route of contamination that resulted in NDMA contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started nearly two years before Defendants' recalls of their MCDs.

335. Thus, prior to initiating recalls of MCDs in the United States, each Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But, each Defendant intentionally or recklessly disregarded that knowledge in making its representations that were false or deceptive about their respective MCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a non-cGMP compliant manner, either of which rendered the MCDs adulterated and misbranded.

336. Defendants' misrepresentations and omissions were material.

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

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

339. But for these misrepresentations and omissions, Plaintiffs and other Class Members would not have paid for Defendants' MCDs. Nor could they have, because the MCDs were adulterated, misbranded, and illegally sold.

340. 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. Nor could they have, because the MCDs were adulterated, misbranded, and illegally sold. To the extent applicable, reliance may be presumed in these circumstances.

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

**SEVENTH COUNT**  
**NEGLIGENT MISREPRESENTATION**  
**AND OMISSION – CONSUMER CLASS**

342. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

343. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except Pharmacy Defendants.

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

345. 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, namely representing that the generic MCDs were the equivalent of the RLDs despite the NDMA contamination and failure to manufacture the MCDs in compliance with the cGMPs, rendering such representations false.

346. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its MCDs, namely failing to disclose that the generic MCDs were not the same as the RLDs as a result of the NDMA contamination and failure to manufacture the MCDs in compliance with cGMPs.

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

348. 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.

349. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

350. Defendant knowingly, recklessly, or negligently represented that its MCDs were manufactured in a cGMP manner and that its MCDs were what they were supposed to be, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls

351. Each Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (if not sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, these and other Defendants knew, and certainly should have known, of the possibility of NDMA creation in their MCDs, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just

like those used by Defendants to make their MCDs. Yet, each Defendant sat by idly and did nothing until the MCD recalls began in 2020.

352. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that NDMA contamination occurred in MCDs potentially due to the same route of contamination that resulted in NDMA contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started nearly two years before Defendants' recalls of their MCDs.

353. Thus, prior to initiating recalls of MCDs in the United States, each Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But, each Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about their respective MCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a non-cGMP compliant manner, either of which rendered the MCDs adulterated and misbranded.

354. 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.

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

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

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

358. Plaintiffs 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.

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

**EIGHTH COUNT**  
**NEGLIGENT MISREPRESENTATION**  
**AND OMISSION – TPP CLASS**

360. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

361. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

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

363. 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.

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

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

366. 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.

367. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine

potential in the event of cGMP deviations or failures concerning quality control and risk management.

368. Defendant knowingly, recklessly, or negligently represented that its MCDs were manufactured in a cGMP manner and that its MCDs were what they were supposed to be, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls

369. Each Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (if not sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, these and other Defendants knew, and certainly should have known, of the possibility of NDMA creation in their MCDs, particularly because regulators including the FDA issued guidance in the second-half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendants to make their MCDs. Yet, each Defendant sat by idly and did nothing until the MCD recalls began in 2020.

370. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that NDMA contamination occurred in MCDs potentially due to the same route of contamination that resulted in NDMA contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started nearly two years before Defendants' recalls of their MCDs.

371. Thus, prior to initiating recalls of MCDs in the United States, each Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But, each Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about their respective MCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a non-cGMP compliant manner, either of which rendered the MCDs adulterated and misbranded.

372. 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.

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

374. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of MCDs, or had reckless disregard for whether they would do so.

375. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have purchased Defendants' MCDS.

376. Plaintiffs 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.

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

**NINTH COUNT**  
**UNJUST ENRICHMENT – CONSUMER CLASS**

378. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

379. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except not under California or New York law against any Defendant.

380. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of paying for Defendants' MCDs, which were falsely represented to be the equivalent of the RLDs but were not as a result of the NDMA contamination and their nonconformance with cGMP.

381. 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.

382. Plaintiffs 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 Master Class Complaint.

383. Plaintiffs 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.

**TENTH COUNT**  
**UNJUST ENRICHMENT – TPP CLASS**

384. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

385. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, to the extent applicable law permits non-consumers to assert this cause of action, and other states' laws other than California's or New York's law.

386. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the paying for Defendants' MCDs, which were falsely represented to be the equivalent of the RLDs but were not as a result of the NDMA contamination and their nonconformance with cGMP.

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

388. Plaintiffs 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 Master Class Complaint.

389. Plaintiffs 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.

**ELEVENTH COUNT**  
**NEGLIGENCE– CONSUMER CLASS**

390. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

391. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except Pharmacy Defendants.

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

393. 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 not contaminated with carcinogenic impurities, complied with cGMPs, and were not adulterated or misbranded.

394. 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 as a result of the NDMA contamination, did not comply with cGMPs, and were adulterated and misbranded as a result of the NDMA contamination and the noncompliance with cGMP, and each was in the best position to uncover and remedy these shortcomings.

395. 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 by introducing non-equivalent, contaminated MCDs into the market.

396. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that their MCDs complied with cGMPs, were not adulterated or misbranded, and were the equivalent of the RLD and not contaminated with carcinogenic impurities.

397. 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 and allowing non-equivalent, contaminated MCDs to be introduced to the market and consumer by Plaintiffs and the Class.

398. 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.

399. Each Defendant, through its affirmative conduct of introducing their MCDs into the stream of commerce, assumed a duty to ensure that their MCDs were manufactured and tested in a non-negligent manner, free of contamination and made within cGMP compliance. By affirmatively representing in their statements and disclosures that their MCDs did not contain any contaminants and were not made in a non-cGMP compliant manner, each Defendant voluntarily assumed duty to exercise reasonable care the distribution and sale of their MCDs and in conveying same to class members or their surrogates.

400. As the manufacturers and/or sellers of medications intended to treat serious medical conditions, including in the case of pharmacy defendants their maintenance of sensitive health information, each Defendant stood in a special relationship with class members by virtue of their superior knowledge and economic position vis-à-vis the true nature of their MCDs.

401. On information and belief, each pharmacy (including Retail Pharmacy Defendants in this case) had purchase agreements with Defendant Manufacturers for MCDs, which included terms requiring that drugs be non-contaminated, made in

accordance with cGMPs, and merchantable. Class members, as ultimate purchasers of MCDs, are intended or incidental third-party beneficiaries of such arrangements.

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

**TWELFTH COUNT**  
**NEGLIGENCE – TPP CLASS**

403. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

404. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

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

406. 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, not contaminated with carcinogenic impurities, complied with cGMPs, and were not adulterated or misbranded.

407. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable payer 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 as a result of the NDMA contamination and the failure to comply with cGMPs and thus were and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

408. 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 by introducing non-equivalent, contaminated MCDs into the market.

409. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that their MCDs complied with cGMPs, were not adulterated or misbranded, and were the equivalent of the RLD.

410. 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 and allowing non-equivalent, contaminated MCDs to be introduced to the market and consumer by Plaintiffs and the Class.

411. Each Defendant breached the 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.

412. Each Defendant, through its affirmative conduct of introducing their MCDs into the stream of commerce, assumed a duty to ensure that their MCDs were manufactured and tested in a non-negligent manner, free of contamination and made within cGMP compliance. By affirmatively representing in their statements and disclosures that their MCDs did not contain any contaminants and were not made in a non-cGMP compliant manner, each Defendant voluntarily assumed duty to exercise reasonable care the distribution and sale of their MCDs and in conveying same to class members or their surrogates.

413. As the manufacturers and/or sellers of medications intended to treat serious medical conditions, including in the case of pharmacy defendants their maintenance of sensitive health information, each Defendant stood in a special relationship with class members by virtue of their superior knowledge and economic position vis-à-vis the true nature of their MCDs.

414. On information and belief, each pharmacy (including Retail Pharmacy Defendants in this case) had purchase agreements with Defendant Manufacturers for MCDs, which included terms requiring that drugs be non-contaminated, made in

accordance with cGMPs, and merchantable. Class members, as ultimate purchasers of MCDs, are intended or incidental third-party beneficiaries of such arrangements.

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

**THIRTEENTH COUNT**  
**NEGLIGENCE PER SE – CONSUMER CLASS**

416. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

417. This cause of action is alleged on behalf of consumer Class Members against all Defendants, except Pharmacy Defendants.

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

419. 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, not contaminated with carcinogenic impurities, complied with cGMPs, and were not adulterated or misbranded.

420. 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, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);

- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and 2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

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

422. 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.

423. Each Defendant, through its affirmative conduct of introducing their MCDs into the stream of commerce, assumed a duty to ensure that their MCDs were manufactured and tested in a non-negligent manner, free of contamination and made within cGMP compliance. By affirmatively representing in their statements and disclosures that their MCDs did not contain any contaminants and were not made in a non-cGMP compliant manner, each Defendant voluntarily assumed duty to exercise reasonable care the distribution and sale of their MCDs and in conveying same to class members or their surrogates.

424. As the manufacturers and/or sellers of medications intended to treat serious medical conditions, including in the case of pharmacy defendants their maintenance of sensitive health information, each Defendant stood in a special relationship with class members by virtue of their superior knowledge and economic position vis-à-vis the true nature of their MCDs.

425. On information and belief, each pharmacy (including Retail Pharmacy Defendants in this case) had purchase agreements with Defendant Manufacturers for MCDs, which included terms requiring that drugs be non-contaminated, made in accordance with cGMPs, and merchantable. Class members, as ultimate purchasers of MCDs, are intended or incidental third-party beneficiaries of such arrangements.

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

**FOURTEENTH COUNT**  
**NEGLIGENCE PER SE – TPP CLASS**

427. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

428. This cause of action is alleged on behalf of TPP Class Members against all Defendants, except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

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

430. 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.

431. 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, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);

- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health—General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);

- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

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

433. 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.

434. Each Defendant, through its affirmative conduct of introducing their MCDs into the stream of commerce, assumed a duty to ensure that their MCDs were manufactured and tested in a non-negligent manner, free of contamination and made within cGMP compliance. By affirmatively representing in their statements and disclosures that their MCDs did not contain any contaminants and were not made in a non-cGMP compliant manner, each Defendant voluntarily assumed duty to exercise reasonable care the distribution and sale of their MCDs and in conveying same to class members or their surrogates.

435. As the manufacturers and/or sellers of medications intended to treat serious medical conditions, including in the case of pharmacy defendants their maintenance of sensitive health information, each Defendant stood in a special relationship with class members by virtue of their superior knowledge and economic position vis-à-vis the true nature of their MCDs.

436. On information and belief, each pharmacy (including Retail Pharmacy Defendants in this case) had purchase agreements with Defendant Manufacturers for MCDs, which included terms requiring that drugs be non-contaminated, made in accordance with cGMPs, and merchantable. Class members, as ultimate purchasers of MCDs, are intended or incidental third-party beneficiaries of such arrangements.

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

**FIFTEENTH COUNT**  
**VIOLATION OF CALIFORNIA'S CONSUMERS LEGAL REMEDIES  
ACT, CAL. CIV. CODE §§ 1750, *ET SEQ.***

438. Plaintiffs hereby incorporate by reference and re-allege herein all paragraphs alleged above.

439. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of California (for the purposes of this count only, "Plaintiffs").

440. Plaintiffs bring this claim individually and on behalf of the members of the proposed California Subclass against Defendants Amneal and Avet (for the purposes of this count only, "Defendants").

441. California's Consumers Legal Remedies Act ("CLRA"), Cal Civ. Code §1750, *et seq.*, prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a).

442. Plaintiffs and members of the California Subclass are "consumers" within the meaning of Cal. Civ. Code § 1761(d) because they bought MCDs for personal, family, or household purposes.

443. Defendants are “persons” within the meaning of California Civil Code sections 1761(c) and 1770 and provided “goods” within the meaning of sections 1761(a) and 1770.

444. Plaintiffs, the other members of the California Subclass, and Defendant have engaged in “transactions,” as that term is defined by California Civil Code § 1761(e).

445. Defendants’ acts and practices, as alleged in this complaint, violate the CLRA because they include unfair and deceptive acts and practices in connection with transactions (the sale of MCDs).

446. As alleged more fully above, Defendants violated the CLRA by falsely representing to Plaintiffs and the other members of the California Subclass that MCDs (i) were the therapeutic equivalent of the RLDs, were not contaminated with carcinogenic impurities, and were manufactured in compliance with cGMPs, and (ii) are generally recognized as safe for human consumption. In fact, the MCDs contained elevated levels of NDMA and were not manufactured in compliance with cGMPs, rendering them non-equivalent to the RLDs and unsafe for human consumption.

447. These misrepresentations constitute “unfair or deceptive acts or practices” that are prohibited by the CLRA, Cal. Civ. Code §§ 1770(a)(5); 1770(a)(7); 1770(a)(9); and 1770(a)(16).

448. Further, Defendants concealed from and failed to disclose to Plaintiffs and the California Subclass that their MCDs did not conform to the product's labels, packaging, advertising, and statements in that they contained elevated levels of NDMA and were not manufactured in accordance with cGMPs, and were therefore not the equivalent of the RLDs, and were not safe for human consumption.

449. Defendants had a duty to disclose to Plaintiffs and members of the California Subclass the true quality, characteristics, ingredients, nutrient levels, and suitability of the MCDs because Defendants were in a superior position to know the true nature of their products and Defendants knew that Plaintiffs and members of the California Subclass could not reasonably have been expected to learn or discover that the MCDs was misrepresented in the packaging, labels, advertising, and websites prior to purchasing the MCDs.

450. The facts concealed or not disclosed by Defendants to Plaintiffs and members of the California Subclass were material in that a reasonable consumer would have considered them important when deciding whether to purchase the MCDs.

451. Plaintiffs and California Subclass members' reliance on these omissions was reasonable given Defendants' advertising, representations, warranties, and general promotions of MCDs.

452. Plaintiffs and members of the California Subclass did not know that Defendants were concealing or otherwise omitting material facts.

453. As a direct and proximate result of Defendants' violations, Plaintiffs and the California Subclass are entitled to injunctive relief ensuring Defendants issue a recall of its MCDs medications and complies with all proper quality and safety standards going forward.

454. On March 27, 2020 and April 7, 2020, prior to filing this action, CLRA notice letters were sent to Defendants that comply in all respects with California Civil Code § 1782(a). Plaintiffs' counsel sent Defendants the letters via certified mail, return receipt requested, advising Defendants that they were in violation of the CLRA and demanding that they cease and desist from such violations. A true and correct copy of Plaintiffs' CLRA letters are attached hereto as **Exhibit 1**.

**SIXTEENTH COUNT**  
**VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW,**  
**CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.***

455. Plaintiffs hereby incorporate by reference and re-allege herein all paragraphs alleged above.

456. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of California (for the purposes of this count only, "Plaintiffs").

457. Plaintiffs bring this claim individually and on behalf of the members of the proposed California Subclass against Defendants Amneal and Avet (for the purposes of this count only, “Defendants”).

458. Defendants are subject to the Unfair Competition Law (“UCL”), Bus. & Prof. Code §§ 17200, *et seq.* The UCL provides, in pertinent part: “Unfair competition shall mean and include unlawful, unfair, or fraudulent business practices and unfair, deceptive, untrue, or misleading advertising.”

459. By committing the acts and practices alleged herein, Defendants violated California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code §§ 17200, *et seq.* as to the Class, by engaging in unlawful, fraudulent, and unfair conduct.

460. Defendants violated the UCL’s proscription against engaging in unlawful conduct as a result of its violations of the CLRA, Cal. Civil Code §§ 1770(a)(5), (a)(7), (a)(9), and (a)(16).

461. Defendants’ acts, omissions, misrepresentations, practices, and non-disclosures concerning the generic MCDs, as alleged herein, also constitute “unlawful” business acts and practices in that they violate the FDCA and implementing regulations, including, at least, the following sections:

- (a) Failure to comply with cGMPs to ensure that the MCDs met safety, quality, purity, identity, and strength standards. 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. § 210.1(a); and

- (b) The prohibition on introduction of adulterated and misbranded medications into interstate commerce. 21 U.S.C. §§ 331, 351-352.

462. Each of Defendants' violations of federal law and regulations violates California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875, *et seq.* (the "Sherman Law"), including, but not limited to, the following sections:

- (a) Section 110100 (adopting all FDA regulations as state regulations);
- (b) Section 111260 ("Any drug or device is adulterated if the methods, 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 the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.");
- (c) Section 111280 ("Any drug is adulterated if it purports to be, or is represented as, a drug that is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the compendium.");
- (d) Section 111295 ("It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.");
- (e) Section 111305 ("It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.");

- (f) Section 111330 (“Any drug or device is misbranded if its labeling is false or misleading in any particular.”);

463. Each of the challenged omissions, statements, and actions by Defendants violates the FDCA and the Sherman Law, and, consequently, violates the “unlawful” prong of the UCL.

464. Defendants’ acts and practices described above violate the UCL’s proscription against engaging in fraudulent conduct.

465. Specifically, Defendants marketed MCDs as the equivalent of RLDs, not containing carcinogenic impurities, and safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants’ MCDs contained elevated levels of NDMA, rendering them inequivalent to the RLDs and unsafe for consumption. These representations were likely to deceive reasonable consumers.

466. Defendants’ acts and practices described above also violate the UCL’s proscription against engaging in unfair conduct.

467. Plaintiffs and the other California Subclass members suffered a substantial injury by virtue of buying MCDs that they would not have purchased (and could not have purchased) absent Defendants’ unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the contaminated nature of its MCDs medication, or by virtue of paying an excessive premium price for the

unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled MCDs medication.

468. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the contaminated nature of the MCDs.

469. Plaintiffs and the other California Subclass members had no way of reasonably knowing that the MCDs they purchased was not as marketed, advertised, packaged, or labeled. Plaintiffs and the other California Subclass members are not able to test for the presence of NDMA in their MCDs. Thus, Plaintiffs and the other California Subclass members could not have reasonably avoided the injury each of them suffered.

470. The gravity of the consequences of Defendants' conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiffs and the other members of the California Subclass.

471. Defendants' violations have continuing and adverse effects because Defendants' unlawful conduct is continuing, with no indication that Defendants intend to cease this fraudulent course of conduct. The public and class members are subject to ongoing harm because numerous Defendants have not issued a recall for its contaminated MCDs medication. Further, although some Defendants have issued

a recall, they have not provided compensation to Plaintiffs for their contaminated MCDs, and Plaintiffs were forced to spend more money to purchase uncontaminated MCDs.

472. Plaintiffs and the California Subclass lost money or property as a result of Defendants' UCL violations because: (a) they would not have purchased MCDs on the same terms if they knew that the MCDs were inequivalent to the RLD because the MCDs contained harmful levels of NDMA, were not manufactured in accordance with cGMPs, and are not generally recognized as safe for human consumption; and (b) the MCDs do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

473. Pursuant to California Business and Professional Code § 17203, Plaintiffs and the California Subclass seek an order of this Court that includes, but is not limited to, an order requiring Defendants to: (a) provide restitution to Plaintiffs and the other California Subclass members; (b) disgorge all revenues obtained as a result of violations of the UCL; and (c) pay Plaintiffs' and the California Subclass' attorney's fees and costs.

**SEVENTEENTH COUNT**  
**VIOLATION OF CALIFORNIA'S FALSE ADVERTISING LAW,  
CAL. BUS. & PROF. CODE §§ 17500, *ET SEQ.***

474. Plaintiffs hereby incorporate by reference and re-allege herein all paragraphs alleged above.

475. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of California (for the purposes of this count only, “Plaintiffs”).

476. Plaintiffs bring this claim individually and on behalf of the members of the proposed California Subclass against Defendants Amneal and Avet (for the purposes of this count only, “Defendants”).

477. California’s False Advertising Law (“FAL”), Cal. Bus. & Prof. Code §§ 17500, *et seq.*, makes it “unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, ... in any advertising device ... or in any other manner or means whatever, including over the Internet, any statement, concerning ... personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.”

478. Defendants committed acts of false advertising, as defined by Cal. Bus. & Prof. Code § 17500, by misrepresenting that the MCDs were the same as the RLDs, were not contaminated with carcinogens, and manufactured in compliance with cGMPs, when in fact, the MCDs were not the same as the RLDs because they were contaminated with NDMA and they were not manufactured in compliance with cGMPs.

479. Defendants knew or should have known, through the exercise of reasonable care, that its representations about the MCDs were untrue and misleading.

480. Defendant's actions in violation of § 17500 were false and misleading such that the general public is and was likely to be deceived.

481. Plaintiffs and the California Subclass lost money or property as a result of Defendants' FAL violations because (a) they would not have purchased the MCDs on the same terms if the true facts were known about the product; (b) they paid a price premium for the MCDs due to Defendants' promises that the MCDs were the same as the RLDs, were not contaminated with carcinogens, and manufactured in compliance with cGMPs; and (c) the MCDs did not have the characteristics as promised by Defendant.

482. Accordingly, Plaintiffs and the California Subclass seek all monetary and non-monetary relief allowed by law, including restitution of all profits stemming from Defendants' unfair, unlawful, and fraudulent business practices; declaratory relief; reasonable attorney's fees and costs under California Code of Civil Procedure § 1021.5; injunctive relief; and other appropriate equitable relief.

**EIGHTEENTH COUNT**  
**VIOLATION OF THE INDIANA DECEPTIVE CONSUMER SALES ACT,  
IND. CODE §§ 24-5-0.5.1, ET SEQ.**

483. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

484. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of Indiana (for the purposes of this count only, “Plaintiffs”), except this Count does not allege a curable deceptive acts claim under Indiana law.

485. Plaintiffs bring this claim individually and on behalf of the members of the proposed Indiana Subclass against the Avet/Granules Defendants (for the purposes of this count only, “Defendants”).

486. Plaintiffs’ purchase of MCDs from Defendants constituted a “consumer transaction.” Ind. Code § 24-5-0.5-2(a)(1).

487. Plaintiffs and Indiana Subclass members are “persons.” Ind. Code § 24-5-0.5-2(a)(2).

488. Defendants are suppliers. Ind. Code § 24-5-0.5-2(a)(3).

489. The Indiana Deceptive Consumer Sales Act (“IDCSA”) is a remedial statute designed to provide remedies to consumers [] for practices that the General Assembly deemed deceptive in consumer transactions.” *Hoopes v. Gulf Stream Coach, Inc.*, 2014 WL 4829623, at \*11 (N.D. Ind. Sept. 29, 2014) (internal citations

removed). Under the IDCSA, “[a] deceptive act is actionable if it is either ‘uncured’ or ‘incurable.’” *Id.*

490. An “uncured” act is one:

- (a) with respect to which a consumer who has been damaged by such act has given notice to the supplier under section 5(a) of this chapter; and
- (b) either:
  - (i) no offer to cure has been made to such consumer within thirty (30) days after such notice; or
  - (ii) the act has not been cured as to such consumer within a reasonable time after the consumer’s acceptance of the offer to cure.

Ind. Code § 24-5-0.5-2(a)(7).

491. “An incurable deceptive act, on the other hand, is one that is done by a supplier as part of a scheme, artifice, or device with intent to defraud or mislead.” *Hoopes*, 2014 WL 4829623, at \*11 (internal quotations omitted).

492. Defendants committed both uncurable and incurable deceptive acts. As alleged herein, Plaintiffs and Indiana Subclass members were damaged by Defendants fraudulent and deceptive conduct. Specifically, Defendants represented that the MCDs were the same as the RLDs, not contaminated with carcinogens like NDMA, and were manufactured in accordance with cGMPs. But, Defendants’ representations were false and misleading because the MCDs were not the same as the RLDs because Defendants’ MCDs that Plaintiffs and Indiana Subclass members

purchased were contaminated with NDMA and not manufactured in compliance with cGMPs.

493. As to uncured deceptive acts, on March 9, 2020, Plaintiffs sent a letter to Defendants on behalf of themselves and members of the Indiana Subclass notifying Defendants of their breaches of the IDCSA. The letter is attached hereto as **Exhibit 1** and complied in all respects with Ind. Code § 24-5-0.5-5(a). No offer to cure was made by Defendants within thirty (30) days, nor has an offer to cure been made to date. Thus, Defendants committed an uncured deceptive act.

494. As to incurable deceptive acts, Defendants acted with an intent to defraud or mislead. Defendants knew or should have known prior to initiating recalls in the United States, about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

495. Defendant knowingly, recklessly, or negligently represented that its MCDs were manufactured in a cGMP manner and that its MCDs were what they were supposed to be, when that was not the case. Rather, each Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have

and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls

496. Each Defendant had direct or constructive knowledge of the risks of NDMA contamination at least as early as 2018 (if not sooner) because of their own recalls of valsartan, losartan, and irbesartan due to nitrosamine contamination. At that time, these and other Defendants knew, and certainly should have known, of the possibility of NDMA creation in their MCDs, particularly because regulators including the FDA issued guidance in the second-half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses just like those used by Defendants to make their MCDs. Yet, each Defendant sat by idly and did nothing until the MCD recalls began in 2020.

497. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that NDMA contamination occurred in MCDs potentially due to the same route of contamination that resulted in NDMA contamination of valsartan, losartan, and irbesartan, which instigated recalls in 2018 and 2019 that started nearly two years before Defendants' recalls of their MCDs.

498. Thus, prior to initiating recalls of MCDs in the United States, each Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the

newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But, each Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about their respective MCDs, namely, that they were not contaminated with nitrosamines and/or were manufactured in a non-cGMP compliant manner, either of which rendered the MCDs adulterated and misbranded.

499. In sum, Defendants also committed incurable deceptive acts.

**NINETEENTH COUNT**  
**VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT,**  
**N.J. STAT. §§ 56:8-1, *ET SEQ.***

500. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

501. This Count is brought by all Plaintiffs listed on this Complaint who are from the State of New Jersey (for the purposes of this count only, “Plaintiffs”).

502. Plaintiffs bring this claim individually and on behalf of the members of the proposed New Jersey Subclass against the Teva and Avet/Granules Defendants (for the purposes of this count only, “Defendants”).

503. Plaintiffs and New Jersey Subclass Members have suffered an injury in fact and lost money or property as a result of Defendants’ violations of New Jersey’s Consumer Fraud Act (“NJCFRA”), N.J. Stat. §§ 56:8-1, *et seq.*

504. The NJCFA protects consumers from “any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission, in connection with the sale or advertisement of any merchandise.” N.J. Stat. § 56:8-2.

505. Defendants engaged in unlawful conduct by deliberately and knowingly engaging in misleading, deceptive, and false statements regarding the generic MCDs in the course of Defendant’s business. Specifically, Defendants represented that the MCDs were the same as the RLDs, were not contaminated with carcinogens like NDMA, and were manufactured in accordance with cGMPs. But in fact, Defendants’ MCDs that Plaintiffs and New Jersey Subclass Members purchased were not the same as the RLDs because they were contaminated with NDMA, a known carcinogen, and not manufactured in accordance with cGMPs.

506. Had Defendants not engaged in these misleading, deceptive, and false practices, Plaintiffs and members of the New Jersey Subclass would not have purchased the MCDs on the same terms and would have paid substantially less for the MCDs.

507. The existence of NDMA in the MCDs, and the fact that the MCDs were not manufactured in accordance with cGMPs, would have been material to Plaintiffs and members of the New Jersey Subclass.

508. Plaintiffs and members of the New Jersey Subclass suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' concealment, misrepresentations, and/or failure to disclose material information in that Plaintiffs and members of the New Jersey Subclass would not have purchased the MCDs on the same terms had they known the truth about the MCDs. Specifically, Plaintiffs and members of the New Jersey Subclass were damaged by the difference in value of the MCDs that were equivalent to the RLDs—which is what Defendants represented the MCDs to be—versus the value of the MCDs had the presence of the NDMA and the failure to manufacture the MCDs in accordance with cGMPs—thus, making the MCDs different from the RLDs—been disclosed, in an amount to be determined through expert testimony and at trial.

509. Pursuant to N.J. Stat. § 56:8-19, Plaintiffs and New Jersey Subclass Members seek an order awarding damages and any other just and proper relief available under the NJCFA.

510. In accordance with N.J. Stat. § 56:8-20, a copy of this complaint will be sent to the New Jersey Attorney General within ten (10) days of filing the same.

### **PRAYER FOR RELIEF**

For these reasons, Plaintiffs pray for the following judgment:

- (a) An order certifying this action as a class action; appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

- (b) A declaration that Defendants are liable under each and every one of the above-enumerated causes of action;
- (c) An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described above, including but not limited to changes to assure Defendants properly manufacture and sell MCDs that are cGMP compliant, and coordinate equitably available remedies such as disgorgement;
- (d) 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; and/or the increases in the amounts paid for non-adulterated, non-misbranded, MCDs in the wake of the recalls and/or the deficient condition of the MCDs;
- (e) 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;
- (f) An award of statutory penalties to the extent available;
- (g) Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and
- (h) Such other and further relief as this Court may deem just, equitable, or proper.

### **JURY DEMAND**

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: February 20, 2025

Respectfully Submitted,

By: /s/ James E. Cecchi

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