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

In re: Valsartan Products Liability Litigation	MDL No. 1:19-md-2875 Honorable Robert B. Kugler, Honorable Joel Schneider,
This document relates to: All Cases	**Master Irbesartan Economic Loss Class Action Complaint** **Jury Trial Demanded**

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CONSOLIDATED (IRBESARTAN)
ECONOMIC LOSS CLASS ACTION COMPLAINT

COME NOW, the Consumer and Third-Party Payor ("TPP") Plaintiffs (collectively the "Class Plaintiffs"), who file this Consolidated Economic Loss Class Action Complaint (Irbesartan) ("Master Class Complaint")[1] against the below-enumerated Defendants.

INTRODUCTION

1. This case arises from adulterated, misbranded, and unapproved irbesartan-containing drugs ("ICDs") that were designed, manufactured, marketed, distributed, packaged, and sold by Defendants (identified and defined infra at Part II.) in the United States, and which have been and remain the subject of one of the largest ongoing contaminated drug recalls ever in the United States. These ICDs are non-merchantable and are not of the quality represented by Defendants named herein.
2. Plaintiffs, by and through their counsel, allege on personal knowledge as to themselves, and on information and belief as to all other matters, as follows against all Defendants named herein.
3. Plaintiffs bring this Complaint as a result of Plaintiffs' exposure to an increased risk of cancers or development of cancers, as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.
4. This Master Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding for claims relating to irbesartan-containing drugs ("ICDs"). It includes allegations involving products designed, manufactured, marketed, distributed, packaged, and sold by various groups of defendants, although not all products and defendants are applicable to every plaintiff with claims in

these proceedings. Plaintiffs seek compensatory and punitive damages, monetary restitution, equitable relief, and all other available remedies as a result of damages caused by Defendants' defective products.

5. This Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court. It is anticipated that putative plaintiffs may adopt this Master Complaint which will specify the particular products and defendants against whom claims are asserted by that putative plaintiff.

6. The Class Plaintiffs bring this economic damages action on behalf of ICD consumers and third party payors who paid or made reimbursements for Defendants' adulterated, misbranded, and/or unapproved ICDs illegally manufactured, sold, labeled, marketed, and distributed in the United States as FDA-approved generic versions of Avapro and Avalide. Defendants' generic ICDs were in fact not FDA-approved generic versions of these drugs and were instead of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with IARC- and EPA-listed probable human carcinogens known as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA").

7. The contamination of Defendants' ICDs began in or around 2011 when Defendants changed the manufacturing process to include a solvent suspected of producing NDMA, NDEA, and potentially other contaminants. Defendants had actual and constructive notice of the contamination as early as 2011.

8. Defendants have been illegally manufacturing, selling, labeling, marketing, and distributing the misbranded and/or adulterated ICDs in the United States since as far back as 2011.

9. The Class Plaintiffs paid for or made reimbursements for generic ICDs that were illegally and willfully introduced into the market by Defendants, causing the Plaintiff Class(es) to sustain economic damages. Defendants' generic ICDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs since at least 2011. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law as set forth herein.
10. This Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those other actions, nor does any Plaintiff or Putative Plaintiff relinquish the right to move to amend their claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each Plaintiff or Putative Plaintiff maintains that ICDs they purchased and/or ingested are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, were manufactured improperly, and lacked proper warnings of the dangers associated with their use.

I. NATURE OF THESE ACTIONS

11. Irbesartan and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Avapro® and Avalide®, respectively. These RLDs are indicated for, *inter alia*, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association.[1] Several million U.S. patients pay for (in whole or in part) and consume generic valsartan each year.

[1] https://www.heart.org/en/news/2018/05/01/more-than-100-million-americans-have-high-blood-pressure-aha-says (last accessed June 5, 2019).

12. According to the Food and Drugs Administration ("FDA") testing, the generic ICDs at issue in this case contained NMBA, NDMA and/or NDEA contamination levels that were in some cases hundreds of times higher than the FDA's February 28, 2019 interim limits for NMBA, NDMA and/or NDEA impurities. The FDA has yet to release testing results for other impurities such as N-Nitroso-N-methyl-4-aminobutyric acid ("NMBA").

13. Upon information and belief, the reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions.[2]

14. Similarly, the reuse of solvents (referred to as the use of "recovered" or "recycled" solvents), can also lead to the presence of nitrosamines in the drugs.[3]

15. Defendants have been illegally manufacturing, selling, labeling, and distributing adulterated generic ICDs in the United States since as far back as March 2012, when the FDA approved the first generic version of Avalide.

16. At all times during the period alleged herein Defendants represented and warranted to consumers and physicians that their generic ICDs were therapeutically equivalent to and otherwise the same as their RLDs, were fit for their ordinary uses, and were manufactured and distributed in accordance with applicable laws and regulations.

17. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic ICDs

[2] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

[3] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine.

were manufactured for import to the United States, and knowingly designed, manufactured, marketed, sold, labeled, packaged, and/or distributed adulterated and misbranded ICDs to Plaintiffs and their prescribing physicians.

18. As a result of Defendants' actions, the Plaintiff Class(es) sustained economic damages.

PARTIES

I. CONSUMER CLASS REPRESENTATIVES

19. Plaintiff N. Albert Bacharach Jr. is a Florida resident and citizen. During the class period, Plaintiff Bacharach paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Bacharach that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Bacharach purchased a product that was not the same as the RLD. Had Plaintiff Bacharach known the product was not the same as the RLD, Plaintiff Bacharach would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Bacharach would not have paid for Defendants' ICDs.

20. Plaintiff Ronald Annis is a Florida resident and citizen. During the class period, Plaintiff Annis paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Annis that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Annis purchased a product that was not the same as the RLD. Had Plaintiff Annis known the product was not the same as the RLD, Plaintiff Annis would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Annis would not have paid for Defendants' ICDs.

21. Plaintiff Brian Wineinger is an Indiana resident and citizen. During the class period, Plaintiff Wineinger paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Wineinger that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Wineinger purchased a product that was not the same as the RLD. Had Plaintiff Wineinger known the product was not the same as the RLD, Plaintiff Wineinger would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Wineinger would not have paid for Defendants' ICDs.
22. Plaintiff Michael Johnson is a New York resident and citizen. During the class period, Plaintiff Johnson paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Johnson that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Johnson purchased a product that was not the same as the RLD. Had Plaintiff Johnson known the product was not the same as the RLD, Plaintiff Johnson would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Johnson would not have paid for Defendants' ICDs.
23. Plaintiff Rachel Miller is a Maryland resident and citizen. During the class period, Plaintiff Miller paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Miller that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Miller purchased a product that was not the same as the RLD. Had Plaintiff Miller known the product was not the

same as the RLD, Plaintiff Miller would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Miller would not have paid for Defendants' ICDs.

24. Plaintiff Charmaine Westry is an Alabama resident and citizen. During the class period, Plaintiff Westry paid money for one or more of Defendants' ICDs, including purchases of ICDs manufactured, distributed, or sold by ZHP Defendants (as defined infra Part III). Defendants expressly and impliedly warranted to Plaintiff Westry that their respective generic ICDs were the same as their RLDs. But in fact, Plaintiff Westry purchased a product that was not the same as the RLD. Had Plaintiff Westry known the product was not the same as the RLD, Plaintiff Westry would not have paid for Defendants' ICDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Westry would not have paid for Defendants' ICDs.

II. THE THIRD PARTY PAYOR ("TPP") CLASS REPRESENTATIVES

25. Plaintiff Maine Automobile Dealers Association, Inc. Insurance Trust is a duly organized and existing 501(c)(9) tax-exempt trust that qualifies as a multiple employer welfare benefit plan or arrangement established or maintained for the purpose of offering or providing health benefits, including prescription drug coverage, to the employees of multiple employers and to their beneficiaries under the authority of the Maine Multiple-Employer Welfare Arrangements law, Title 24-A, Chapter 81, §§ 6601-6616 of the Maine Revised Statutes Annotated and the Employee Retirement Income Security Act of 1974. The Trust was organized in Maine and has its principal place of business in Maine.

26. The Trust administers a multiple-employer welfare arrangement for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance.

27. The Trust provides health benefit coverage, including a prescription drug benefit, to its members. The Trust's members received prescriptions for and it paid for ICDs listed as recalled by the United States Food and Drug Administration and that were manufactured, distributed, or sold by at least the ZHP Defendants, the Mylan Defendants, the Aurobindo Defendants, and the Torrent Defendants (as defined infra Part II.C).

III. DEFENDANTS

28. Defendants are comprised of entities at various points in the manufacture, labeling, packaging, and distribution chain.

29. Active Pharmaceutical Ingredient manufacturers ("API manufacturers") then sell to Finished Dose Manufacturers, who then sell the ICDs to unique labelers/distributors, as well as repackagers, who then distribute and sell the drugs to pharmacies, who dispense them to patients, such as Plaintiffs.

A. Zhejiang Huahai Pharmaceutical Co., Ltd and Related Defendants

30. Upon information and belief, much of the ICDs manufactured by the ZHP Defendants contains NDMA levels ***hundreds of times*** higher than acceptable limits for human consumption, according to laboratory results published by the FDA in regards to Valsartan.[4] Some of its ICDs also contained NDEA.[5]

i. Zhejiang Huahai Pharmaceutical Co., Ltd

31. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The

[4] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last accessed June 5, 2019).
[5] Torrent has only recalled ICDs by ZHP.

company also has a United States headquarters located at 2009 and 2002 Eastpark Blvd., Cranbury, NJ 08512. ZHP on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, ZHP has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic ICDs throughout the United States.

32. Zhejiang Huahai Pharmaceutical Co., Ltd. is the parent company of subsidiaries Prinston Pharmaceutical Inc., Solco Healthcare, LLC, and Huahai U.S., Inc.

33. The ICDs made by Zhejiang Huahai Pharmaceutical Co. Ltd. are distributed in the United States by Prinston Pharmaceuticals dba Solco Healthcare, LLC.[6]

ii. Huahai U.S., Inc.

34. Defendant Huahai US Inc. ("Huahai US") is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Huahai US is the wholly-owned subsidiary of ZHP. Huahai US "focus[es] on the sales and marketing of [ZHP's] APIs and Intermediates."[7] At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States.

35. Defendant Huahai US Inc. is a subsidiary of Zhejiang Huahai Pharmaceutical Ltd., Co.

iii. Prinston Pharmaceutical, Inc. d/b/a Solco Healthcare US LLC

36. Defendant Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston") is a Delaware corporation with its principal place of business located at 2002 Eastpark Blvd.,

[6] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm;
[7] Huahai US, HOMEPAGE, https://www.huahaius.com/index.html (last accessed Apr. 5, 2019).

Cranbury, New Jersey 08512. Defendant Prinston is a majority-owned subsidiary of ZHP. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States.

37. Solco Healthcare U.S., LLC is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical Co, Ltd.

38. Defendant Prinston Pharmaceutical, Inc. manufactured ICDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.8

iv. Solco Healthcare US, LLC

39. Defendant Solco Healthcare US, LLC ("Solco") is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Solco is a wholly-owned subsidiary of Prinston and ZHP. At all times material to this case, Solco has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic ICDs in the United States.

B. Aurobindo Pharma, LTD. and Related Defendants

i. Aurobindo Pharma, LTD.

40. Defendant Aurobindo Pharma, Ltd. ("Aurobindo") is a foreign corporation with its principal place of business at Plot no. 2, Maitrivihar, Ameerpet, Hyderabad-500038 Telangana, India, and a United States headquarters at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Aurobindo has been engaged in the

[8] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs throughout the United States.

ii. Aurobindo Pharma, USA, Inc.

41. Defendant Aurobindo Pharma USA Inc. is a company, with its principal place of business located at 279 Princeton Hightstown Road East Windsor, NJ 08520. Aurobindo Pharma USA Inc. is the wholly owned subsidiary of Aurobindo. "Aurobindo Pharma Limited is voluntarily recalling 22 Batches of the drug substance Irbesartan due to the presence of an impurity, N-nitrosodiethylamine (NDEA)". At all times material to this case, Aurobindo Pharma USA Inc. has been engaged in the manufacture, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs in the United States.

iii. Aurolife Pharma, LLC

42. Defendant Aurolife Pharma, LLC ("Aurolife") is a Delaware limited liability company with its principal place of business at 2400 US- 130, North, Dayton, New Jersey 08810. It is a wholly owned subsidiary of Aurobindo USA. At all times material to this case, Aurolife has been engaged in the manufacturing, sale, and distribution of ICDs in the United States.

43. Collectively Aurobindo, Aurobindo Pharma USA Inc. and Aurolife will be referred to as the Aurobindo Defendants in this Complaint.

44. Aurobindo supplies active pharmaceutical ingredients ("API"), including Irbesartan API, to United States manufacturers, who in turn produce finished product, with the expectation and actual knowledge that its API will be purchased and/or used in other drug products purchased throughout the United States, including within the State of Florida and within this District.

iv. SciGen Pharmaceuticals Inc., US

45. ScieGen Pharmaceuticals Inc U.S. ("ScieGen") is corporation, with its principal place of business at 89 Arkay Drive Hauppauge, NY 11788. ScieGen is a "fast growing generic pharmaceutical company" whose "core business is in the area of Development, manufacturing, marketing and Distribution of high quality and cost effective generic pharmaceutical products."

46. At all times material to this case, ScieGen has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic Irbesartan-containing drugs ("ICDs").

47. SciGen Pharmaceuticals Inc., U.S. Supplied Irbestartan to Westminster Pharmaceuticals and Golden State Medical Supply Inc.

v. Westminster Pharmaceuticals

48. Westminster Pharmaceuticals ("Westminster") is a corporation, with its principal place of business at 1321 Murfreesboro Pike, Suite 607, Nashville, TN 37217.

49. At all times material to this case, Westminster has engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs in the United States, including the state of New Jersey.

vi. Golden State Medical Supply

50. Golden State Medical Supply ("Golden State") is a corporation, with its principal place of business at 5187 Camino Ruiz Camarillo, CA 93012.

51. At all times material to this case, Golden State has engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic ICDs in the United States, including the state of New Jersey

C. Pharmacy Defendants

i. Aetna RX Home Delivery, LLC

a. Defendant, Aetna RX Home Delivery, LLC is a Delaware corporation or a Pennsylvania corporation with its principal place of business located at 151 Farmington Avenue in Hartford, Connecticut.

52. Upon information and belief, Defendant Aetna RX Home Delivery, LLC sold thousands of the adulterated and/or misbranded ICDs to U.S. consumers such as Plaintiffs

ii. Walgreen Co.

53. Defendant Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015.

54. Upon information and belief, Defendant Walgreens Co. sold thousands of the adulterated and/or misbranded ICDs to U.S. consumers such as Plaintiffs

iii. Walgreens Boots Alliance, Inc.

55. Walgreens Boots Alliance, Inc. is the parent Corporation of Defendant Walgreen Co.

56. Walgreens Boots Alliance, Inc. is Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

57. Walgreen Co. and Walgreens Boots Alliance, Inc. are collectively referred to within this Complaint as "Walgreens."

58. Walgreens is one of the retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states including the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five 5 miles of a store location. In addition, Walgreens recently purchased an additional 1,932 store locations from rival Rite Aid Corporation, further consolidating the industry.

Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for prescription sales. Walgreens accounts for nearly 20% of the U.S. market for retail prescription drug sales.

59. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

60. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy.

61. Upon information and belief, Defendant Walgreens sold thousands of the adulterated and/or misbranded ICDs to U.S. consumers such as Plaintiffs.

iv. Wegmans

62. Defendant Wegmans and/or Wegmans Food Market Inc.. collectively referred to as Wegmans is a New York corporation, with its principal place of business in New York. Its corporate office is located at 1500 Brooks Avenue, PO Box 30844, Rochester NY 14603-0844.

63. Upon information and belief, Defendant Wegmans sold thousands of the adulterated and/or misbranded ICDs to U.S. consumers such as Plaintiffs.

v. Wal-Mart, Inc.

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

65. Upon information and belief, Defendant Wal-Mart, Inc. (including Sam's Club) sold thousands of the adulterated and/or misbranded ICDs to U.S. consumers such as Plaintiffs.

D. Wholesaler Defendants

66. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

67. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

68. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

69. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

i. Cardinal Health, Inc.

70. As mentioned above, Defendant Cardinal Health, Inc. is a corporation, with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.[9]

ii. McKesson Corporation

71. Upon information and belief, Defendant McKesson Corporation is a Delaware corporation with its principal place of business located at 6535 North State Highway 161, Irving, Texas 75039.

[9] https://www.theharvarddruggroup.com/shop/contact/index

iii. AmerisourceBergen Corporation

72. Defendant AmerisourceBergen Corp. is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087.

E. Doe Defendants

73. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of DOES 1 through 100, inclusive, are unknown to Plaintiffs at this time, who therefore sue defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiffs for the acts and omissions alleged herein below, and the resulting injuries to Plaintiffs, and damages sustained by the Plaintiffs. Plaintiffs will amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

74. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE Defendants, and each of them, and at all said times, each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

JURISDICTION AND VENUE

75. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28U.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.

76. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the states where venue for each action is proper. At all relevant times Defendants transacted, solicited, and conducted business throughout the entirety of the United States and specifically in the specific jurisdictions noted by Plaintiffs in their Short Form Complaints through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in the states where venue for each action is proper.

77. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the states in which Plaintiffs reside and were injured, and they are all subject to personal jurisdiction in this District.

THE IRBESARTAN-CONTAINING DRUGS

78. The medication in question in this case is a drug that Defendants marketed and sold under the name "irbesartan."

79. Irbesartan is a generic version of the brand-name medication, Avapro, and irbesartan combined with hydrochlorothiazide (HCTZ) is a generic version of Avalide.

80. Irbesartan is used to treat high blood pressure and heart failure, and to improve a patient's chances of living longer after a heart attack.

81. Irbesartan is classified as an angiotensin receptor blocker (ARB) that is selective for the type II angiotensin receptor. It works by relaxing blood vessels so that blood can flow more easily, thereby lowering blood pressure.

82. Irbesartan can be sold by itself or as a single pill which combines irbesartan with HCTZ.

83. The drug binds to angiotensin type II receptors (AT1), working as an antagonist.

84. The patents for Avapro and Avalide expired in March 2012.[10]

85. Shortly after the patents for Avapro and Avalide expired, the FDA began to approve generic versions of the drugs.

I. NDMA

86. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[11]

87. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[12]

88. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

89. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[13]

90. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[14] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental

[10] https://www.fiercepharma.com/special-report/avapro.
[11] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.
[12] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[13] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[14] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[15]

91. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[16]

92. Exposure to high levels of NDMA has been linked to liver damage in humans.[17]

93. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[18]

94. Other studies showed an increase in other types of cancers, including but not limited to, stomach, colorectal, intestinal, and other digestive tract cancers.

95. On July 27, 2018, the FDA put out a press release, explaining the reason for its concern regarding the presence of NDMA found in valsartan-containing drugs. In those statements, it provided, in relevant part:

> NDMA has been found to increase the occurrence of cancer in animal studies…Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.[2]
> …
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.[19]

[15] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[16] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[17] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[18] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.
[19] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

96. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[20]

II. NDEA

97. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[21]

98. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[22]

99. NDEA is an even more potent carcinogen than NDMA.

100. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

101. Hematological effects were also reported in animal studies.[23]

102. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure[24]

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[20] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[21] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[22] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; *see also* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.
[23] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[24] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

103. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[25]

104. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[26]

105. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[27]

III. NMBA

106. NMBA is another nitrosamine identified in sartan medications by the FDA.[28]

107. Due to its structural similarities to NDMA and NDEA, NMBA is considered by international regulators such as the World health Organization to have a similar toxicological profile to NDMA and NDEA.[29]

108. When NMBA was first discussed in an FDA press release, FDA noted, "We are deeply concerned about the presence of a third nitrosamine impurity in certain ARB medications, but it's important to underscore that, based on the FDA's initial evaluation, the increased risk of cancer to patients with NMBA exposure appears to be the same for NDMA exposure but less than the risk from NDEA exposure. That said, any presence of such impurities in drug products is not acceptable."[30]

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[25] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[26] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[27] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[28] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[29] https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en/.
[30] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine.

109. Thus, the FDA set interim consumption limits of NMBA at 96 nanograms per day, which is the same interim level set for daily consumption of NDMA.[31]

110. Like NDMA and NDEA, NMBA has been a chemical of choice used in animal studies to induce cancer in animal study subjects, because it is known to induce cancer.[32]

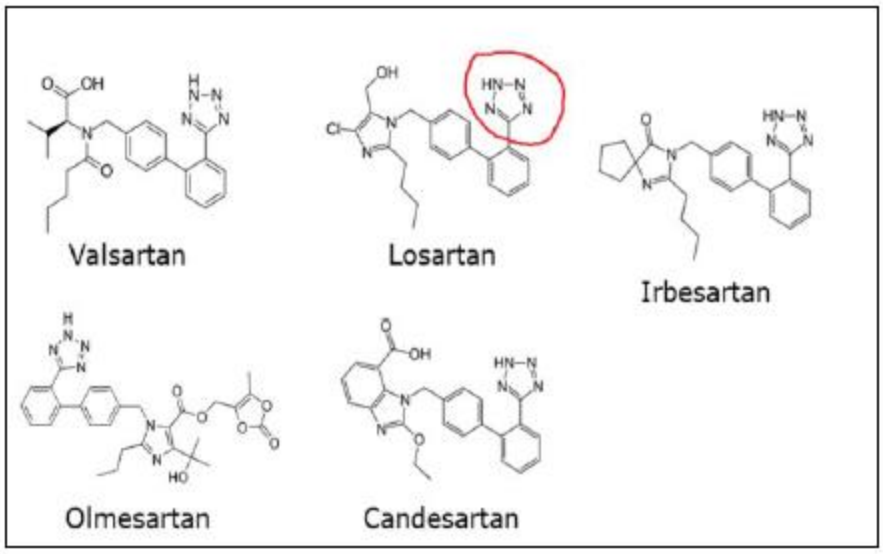
111. Testing and evaluation is ongoing of ICDs manufactured, distributed, or sold by Defendants. Besides these nitrosamines, ongoing investigation suggests other impurities, such as NMBA, may exist as well in the ICDs at issue.

IV. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

112. These nitrosamines are considered genotoxic compounds, as they all contain nitroso groups, which are gene-mutating groups.[33]

113. N-nitrosamines are formed at the tetrazole ring present in ARB medications, including valsartan, losartan, and irbesartan. The tetrazole ring is visually depicted in the following diagram[34]:

[31] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[32] https://pubmed.ncbi.nlm.nih.gov/3180095/.
[33] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[34] Committee for Medicinal Products for Human Use, Assessment Report Article 31 Angiotensin-II-Receptor Antagonists (sartans) Containing a Tetrazole Group, at 3-4 (European Medicines Agency 2019).

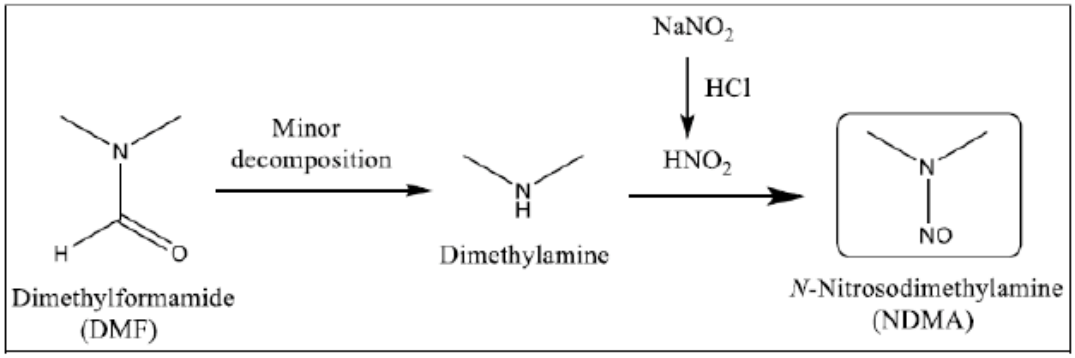


114. N-nitrosamines are formed as part of the synthetic process or through introduction of N-nitrosamines through use of recovered solvents.

115. As to the synthetic process, "formation of N-nitrosamines is only possible in the presence of a secondary or tertiary amine and nitrite, usually under acidic reaction conditions."[35]

116. NDMA is derived from the decomposition of dimethylformamide (DMF) at high temperatures to dimethylamine (DMA). DMA acts as the secondary amine leading to formation of NDMA, as shown in the following diagram:

Fig.: 2 Formation of NDMA from DMF

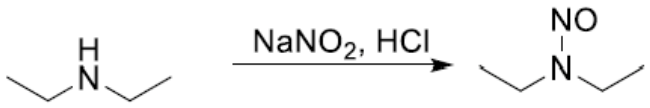


[35] *Id.* at 5.

117. DMA may also be present as an impurity in DMF as it is a precursor in the industrial DMF synthetic process, which can then lead to formation of NDMA in the ARB drugs. DMA "may also be a degradant formed during storage of the solvent, potentially present as the formate salt."[36]

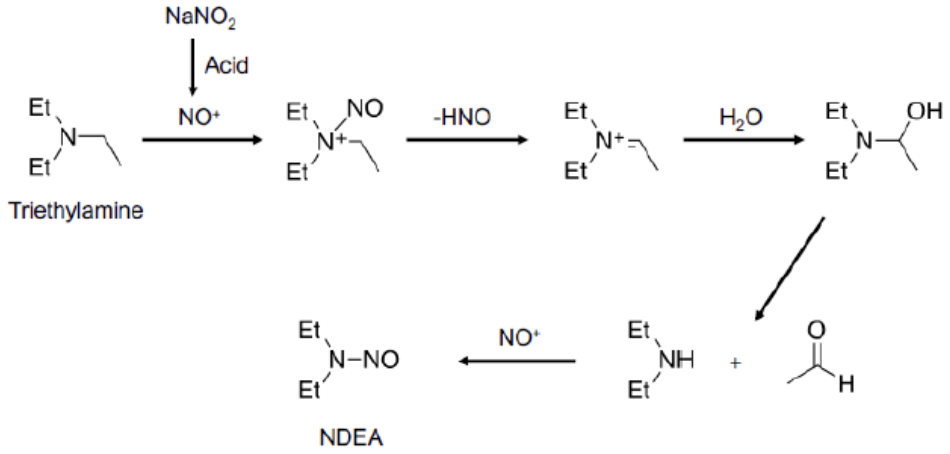
118. NDEA is "generated from diethylamine (DEA) by analogy to the formation of NDMA from DMA," as depicted in the following diagram[37]:

Fig.: 3 General reaction scheme for formation of NDEA from diethylamine



119. Alternatively, "direct nitrosation of TEA may occur via a nitrosoiminium ion, resulting in the generation of an aldehyde and a secondary amine, which reacts with further nitrous acid to form a nitrosamine."[38]

Fig. 4: Nitrosative cleavage of TEA to DEA followed by nitrosation to NDEA



[36] *Id.*
[37] *Id.*
[38] *Id.* at 6.

120. Upon information and belief, the nitrosamine contamination in the LCDs/ICDs is also the result of the API Manufacturer Defendants utilizing recycled or recovered solvents during the manufacture of the Active Pharmaceutical Ingredient ("API").

121. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[39]

V. RECALLS

122. Recalls of ARB drugs due to nitrosamine contamination initially began after nitrosamine impurities were discovered in valsartan-containing drugs on or around July 2018.[40] Since that time, the regulatory investigation broadened to include other ARB drugs, including valsartan and losartan.

A. Valsartan Recalls

123. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[41] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[42]

[39] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.
[40] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[41] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[42] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

124. The recall notice further stated, "Zhejiang Huahai Pharmaceuticals has stopped distributing its valsartan API and the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products."[43]

125. As of September 28, 2018, FDA placed Zhejiang Huahai Pharmaceuticals Co, Ltd. on import alerts, which halted all API made by the company from entering the United States. This was the product of an inspection of Zhejiang Huahai's facility.[44]

126. FDA's recall notice also stated that the presence of NDMA in the valsartan-containing drugs was "thought to be related to changes in the way the active substance was manufactured."[45]

127. The recall was limited to "all lots of non-expired products that contain the ingredient valsartan supplied to them by [the Active Pharmaceutical Manufacturer (API)] supplied by this specific company."

128. On July 18, 2018, FDA put out another press release about the recall, noting its determination that "the recalled valsartan products pose an unnecessary risk to patients."[46]

129. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow.

130. On August 9, 2018, FDA announced that it was expending the recall to include valsartan-containing products manufactured by another API manufacturers, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained

[43] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[44] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[45] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[46] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

unacceptable levels of NDMA.[47] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[48]

131. On October 5, 2018, FDA posted the results of some testing conducted on samples of recalled valsartan tablets. Noting that "consuming up to 0.096 micrograms of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure," the results of the testing showed levels ranging from 0.3 micrograms up to 17 micrograms[49] (emphasis added). Thus, the pills contained somewhere between 3.1 and 177 times the level of NDMA deemed safe for human consumption. Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the safe level.

132. By way of comparison, NDMA is sometimes also found in water and foods, including meats, dairy products, and vegetables. The U.S. Health Department set strict limits on the amount of NDMA that is permitted in each category of food, but these limits are dwarfed by the amount of NDMA present in the samples of the valsartan-containing medications referenced above. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[50]

133. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall notices also stated that the recalls related to unexpired valsartan-containing products.[51]

[47] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[48] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[49] https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm.
[50] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[51] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

134. On November 29, 2018, FDA sent a warning letter to Mr. Jun Du, Executive Vice President of ZHP, citing the company for numerous cGMP violations relating to its API, noting that ZHP's API was adulterated under the Federal Food Drug, and Cosmetic Act.[52] The Warning Letter cited ZHP's failure to investigate quality-related complaints, failure to investigate out-of-specification test results, failure to evaluate the potential effect of changes in the manufacturing process, and failure to implement effective quality systems.

135. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."[53]

136. These recalls have continued through the first half of 2019 and may continue past the date upon the filing of this Complaint.

B. Losartan Recalls

137. On November 9, 2018, Defendant Sandoz, Inc. voluntarily recalled one lot of losartan, noting that the API was sourced from by Defendant Zhejiang Huahai Pharmaceuticals Co., Ltd.

138. In December of 2018 Torrent recalled some of its of losartan-containing drugs. Torrent expanded its recall of losartan-containing drugs in January, March, April and

[52] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018

[53] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

September of 2019. Defendant Torrent Pharmaceuticals purchased its API from Defendant Hetero Labs. Defendants AvKare, RemedyRepack, Inc. Preferred Pharmaceuticals, Inc. and Legacy Pharmaceutical Packaging, LLC are a few of the labelers and repackagers who get their losartan-containing drugs from Torrent.

139. On February 25, 2019, the Macleods Defendants recalled certain losartan-containing drugs with API also purchased from Defendant Hetero Labs, Ltd.

140. On March 1, 2019, Defendant Hetero and its distributor, Camber, issued a recall for many of its losartan-containing drugs. Defendant Camber supplied losartan-containing drugs to both Legacy Pharmaceutical Packaging, LLC and HJ Harkins Co. d/b/a Pharm Pac.

141. On April 29, Defendant Teva also recalled losartan-containing drugs and subsequently expanded its scope. The API in Teva's products was purchased from Defendant Hetero Labs, Ltd. Defendant Teva supplied losartan-containing drugs to Defendant Golden State Medical Supply.

142. On May 6, 2019, Defendant Vivimed Life Sciences issued a recall. Defendant Vivimed's API was also sourced from Hetero Labs, Ltd. and was subsequently distributed, labeled, and/or packaged by Defendant Heritage Pharmaceuticals, Inc.

143. On October 8, 2019, FDA sent a Warning Letter to Torrent Pharmaceuticals, Limited, citing the company with numerous "significant" violations of cGMPs relating to their losartan-containing drugs. Specifically, FDA noted that Torrent failed to follow its process validation protocol and after multiple batches of API failed tests, Torrent developed alternate protocols to "justify commercial use of the alternate API, even though [Torrent] had data demonstrating [its] process was not capable of producing quality material using the new alternate API."

C. Irbesartan Recalls

144. On October 30, 2018 ScieGen issued the first recall of irbesartan-containing drugs. The API was purchased from Aurobindo, and the finished pills were then sold to, packaged, and/or labeled by Defendants Westminster Pharmaceuticals and Golden State Medical Supply.

145. On January 18, 2019, Solco also added lots of irbesartan-containing drugs to the recall list. Solco's irbesartan-containing drugs contained API which had been purchased from ZHP.

D. Recalls in Other Countries

146. The European Medicines Agency (EMA) also recalled many batches of valsartan-containing drugs. According to the agency, "[t]he review of valsartan medicines was triggered by the European Commission on 5 July 2018…On 20 September 2018, the review was extended to include medicines containing cadesartan, irbesartan, and olmesartan."[54]

147. In light of the EMA's findings, Zhejiang Huahai Pharmaceutical Co., Ltd., along with another API manufacturer, Zhejiang Tianyu, are not presently authorized to produce valsartan for medications distributed in the European Union.[55]

148. Health Canada also issued a recall of valsartan-containing medications on July 9, 2018, noting the presence of NDMA as the reason. Health Canada similarly stated that NDMA

[54] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.
[55] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines.

is a potential human carcinogen.[56] Similarly, multiple batches of irbesartan[57] was subsequently recalled.

E. Defendants Had Actual and/or Constructive Notice of NDMA and/or NDEA Contamination of their ICDs

149. The FDA has concluded that "NDMA and NDEA are probable human carcinogens and should not be present in drug products." As alleged above, the ICDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDMA, NDEA, and NMBA, sometimes reaching levels hundreds of times higher than the FDA's interim safety limits.

150. NDMA, NDEA, and NMBA are not FDA-approved ingredients for DIOVAN, EXFORGE, or their generic equivalents. Moreover, none of Defendants' ICDs identify NDMA, NDEA, or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogens and are not approved to be included in valsartan API.

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

152. ZHP changed its valsartan manufacturing processes in or about 2012, if not earlier. It is not yet known when the processes changed at Defendants' other API manufacturing facilities.

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[56] http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem.

[57] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69668a-eng.php.

153. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after [ZHP] introduced changes to its manufacturing process in 2012."[58]

154. Most assuredly, NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, or their generic equivalents. None of Defendants' ICDs identifies NDMA, NDEA, or any other nitrosamine as an ingredient on the products' labels or elsewhere.

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

156. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

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

21 C.F.R. § 211.110(c).

157. And as shown below, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

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[58] *See* European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, *at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_003000.jsp&mid=WC0b01ac058004d5c1 (last accessed June 5, 2019).

158. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' ICDs would have been discovered in much sooner (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their ICDs were adulterated and/or misbranded and misbranded as early as 2012 when ZHP first discovered or should have discovered nitrosamines in its valsartan API.

159. However, there are indications that Defendants had actual knowledge of their ICDs' contamination with nitrosamines, and made efforts to conceal or destroy the evidence.

160. As alleged above, FDA investigators visited ZHP's facilities in May 2017. In the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing," and routinely disregarded sampling anomalies suggestive of impurities.

161. These discoveries by the FDA's investigators suggest that ZHP and Defendants were specifically aware of impurities in the drugs being manufactured by ZHP. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated and/or misbranded ARB drugs into the U.S. market.

162. Defendants were or should have been aware of ZHP's cGMP violations as early as 2012, if not earlier.

163. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical. All of these entities should be imputed with actual knowledge of ZHP's willful deviations from cGMPs because of their corporate affiliations and overlapping operations and employees or agents. For instance, Solco and Huahai US have offices in the same office building in Cranbury, New Jersey.

164. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated and/or misbranded medications containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their generic ICDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their ICDs only after the FDA had threatened an involuntary recall.

THE FEDERAL REGULATORY LANDSCAPE

I. THE GENERIC MEDICATION IS SUPPOSED TO BE CHEMICALLY THE SAME AS A BRAND NAME.

165. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[59]

166. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.

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[59] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last accessed June 5, 2019) (emphasis in original).

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[60]

167. The drugs purchased and/ or ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

168. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[61]

169. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[62]

II. MISBRANDED AND ADULTERATED DRUGS

170. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[63]

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[60] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ ucm167991.htm.

[61] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

[62] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

[63] 21 U.S.C. § 331(g).

171. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[64]

172. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[65]

173. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[66]

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[67]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[68]

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[69]

174. A drug is misbranded:

[64] 21 U.S.C. § 331(a).
[65] 21 U.S.C. § 331(c).
[66] 21 U.S.C. § 351(a)(2)(A).
[67] 21 U.S.C. § 351(a)(2)(B).
[68] 21 U.S.C. § 351(b).
[69] 21 U.S.C. § 351(d).

a. "If its labeling is false or misleading in any particular."[70]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[71]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[72]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. …"[73]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[74]

f. "if it is an imitation of another drug;"[75]

g. "if it is offered for sale under the name of another drug."[76]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[77]

[70] 21 U.S.C. § 352(a)(1).
[71] 21 U.S.C. § 352(c).
[72] 21 U.S.C. § 352(e)(1)(A)(ii)
[73] 21 U.S.C. § 352(f).
[74] 21 U.S.C. § 352(g).
[75] 21 U.S.C. § 352(i)(2).
[76] 21 U.S.C. § 352(i)(3).
[77] 21 U.S.C. § 352(j).

i. If the drug is advertised incorrectly in any manner;[78] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[79]

175. As articulated in this Complaint, Defendants' unapproved drug was adulterated and/or misbranded in violation of all of the above-cited reasons.

III. THE DRUGS PURCHASED AND/OR INGESTED BY PLAINTIFFS WERE NOT IRBESARTAN, BUT NEW, UNAPPROVED, IRBESARTAN -CONTAINING DRUGS

176. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[80]

177. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[81]

178. NDMA, NDEA, NMBA, and other nitrosamines each have the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the

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[78] 21 U.S.C. § 352(n).
[79] 21 U.S.C. § 352(p).
[80] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.
[81] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.

human body, and thus, NDMA, NDEA, and NMBA are, by definition, active ingredients in a drug.

179. FDA further requires that whenever a new, active ingredient is added to a drug, then the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[82]

180. Failure to Adhere to the terms of an ANDA Approval, or Alternatively, Failure to Obtain FDA Approval for a New Drug Deprives the Manufacturer of the Shield of Federal Preemption under Pliva v. Mensing, 564 U.S. 604 (2011).

181. In Mensing, the Supreme Court held that a state law claim which required generic manufacturers to use a different, stronger label was preempted. See generally, Pliva v. Mensing, 564 U.S. 604 (2011). The Court so held because generic labels are required to be the same as the corresponding brand-name labels. See id.

182. However, when a generic manufacturer ceases to manufacture a drug that meets all terms of its approval, or 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.

183. This new and unapproved drug cannot be required to have the same label as the brand-name drug, as the two products are no longer the same. Thus, the manufacturer forfeits the shield of federal preemption.

184. Therefore, Plaintiffs' state-law claims asserted herein do not conflict with the federal regulatory scheme.

[82] *See* 21 C.F.R. § 310.3 (h).

185. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are deemed to be adulterated under federal law, and the sale or introduction into commerce of adulterated drugs is illegal.[83] Thus, a plaintiff bringing a state-law tort claim premised upon this violation is not asking the manufacturer to do anything different than what federal law already requires.

186. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

187. Because the ICDs purchased and/or ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

IV. FAILURE TO ADHERE TO THE TERMS OF AN ANDA APPROVAL, OR ALTERNATIVELY, FAILURE TO OBTAIN FDA APPROVAL FOR A NEW DRUG DEPRIVES THE MANUFACTURER OF THE SHIELD OF FEDERAL PREEMPTION UNDER *PLIVA V. MENSING*, 564 U.S. 604 (2011).

188. In *Mensing*, the Supreme Court held that a state law claim which required generic manufacturers to use a different, stronger label was preempted. *See generally, Pliva v. Mensing*, 564 U.S. 604 (2011). The Court so held because generic labels are required to be the same as the corresponding brand-name labels. *See id.*

189. However, when a generic manufacturer ceases to manufacture a drug that meets all terms of its approval, or 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.

[83] *See generally,* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

190. This new and unapproved drug cannot be required to have the same label as the brand-name drug, as the two products are no longer the same. Thus, the manufacturer forfeits the shield of federal preemption.

191. Therefore, Plaintiffs' state-law claims asserted herein do not conflict with the federal regulatory scheme.

192. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are deemed to be adulterated under federal law, and the sale or introduction into commerce of adulterated drugs is illegal.[84] Thus, a plaintiff bringing a state-law tort claim premised upon this violation is not asking the manufacturer to do anything different than what federal law already requires.

193. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

194. Because the ICDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

V. DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF ITS IRBESARTAN -CONTAINING DRUGS

195. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[85] and conform to requirements governing the appearance of the label.[86]

[84] *See generally,* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.
[85] 21 C.F.R. § 201.5.
[86] 21 C.F.R. § 801.15.

196. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[87] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

197. "Most, if not all, labeling is advertising. The term "labeling" is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[88]

198. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[89]

199. Because NDMA and/or NDEA were not disclosed by Defendants as ingredients in the irbesartan-containing drugs purchased and/or ingested by Plaintiffs, the subject drugs were misbranded.

200. It is unlawful to introduce a misbranded drug into interstate commerce.[90] Thus, the irbesartan-containing drugs purchased and/or ingested by Plaintiffs were unlawfully distributed and sold.

VI. BACKGROUND ON GOOD MANUFACTURING PRACTICES ("CGMPS")

201. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. See 21 U.S.C. § 351(a)(2)(B).

202. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used

[87] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[88] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[89] 21 C.F.R. § 201.6; 201.10.
[90] 21 U.S.C. § 331(a).

for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

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

204. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. See 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

205. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

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

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
>
> 21 .F.R. § 211.22(a).

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

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

209. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

VII. THE GENERIC DRUG APPROVAL FRAMEWORK

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

211. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

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

213. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

A. ANDA Applications Must Demonstrate Bioequivalence

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

to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

215. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

a. a full description of the drug's substance, including its physical and chemical characteristics and stability; and

b. the specifications necessary to ensure the identify strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

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

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

iv. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes

218.

219. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

220. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

221. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process which ensures that the manufacturing process produces a dosage that meets product specifications.

v. ANDA Applications Must Comply with cGMPs

222. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPS.

223. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

vi. ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness

224. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[91] branded drug. Pharmacists, physicians, and patients

[91] The FDA's Drug Glossary defines an RLD as follows: "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

can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., irbesartan or irbesartan HCTZ), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

225. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or 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.

226. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

227. According to the FDA, there are at least twenty one ANDAs approved for generic Avapro, eighteen for generic Avalide.

B. Starting as Early as 2007, Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities

228. For some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than

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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."

their branded equivalents or domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

229. Defendants' foreign manufacturing operations were no exception to this.

i. ZHP's Inadequate Manufacturing Processes

230. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and it remains one of China's largest exporters of pharmaceuticals to the United States and the European Union.

231. ZHP serves as a contract API manufacturer of numerous defendants' ARB drugs in this MDL (including for valsartan, and irbesartan) as set forth in this Complaint and the other operative Long Form Complaints in this MDL, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

232. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

233. On or about March 27-30, 2007, the FDA inspected ZHP's Xunqiao Linhai City facilities. That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the facility. Those deviations supposedly were later corrected by ZHP. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

234. The FDA inspected ZHP's same Xunqiao facility again on November 14-18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed."

Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

235. On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its valsartan API at this Chuannan facility. That inspection resulted in the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter and investigation up to that point. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated." These findings were not made fully available to the public. However, this information was shared or available to ZHP's finished-dose manufacturers, as well as those Defendants further down the distribution chain.

236. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. . . . . To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts . . . . From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees results. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.' Specifically, this 85% was further broken down into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was provided to

the consignee without a response and the consignee failed to respond but continued to purchase API from [ZHP]."[92]

237. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment" surrounding the facility. These manipulations of sampling were components of a pattern and practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA, NDEA, and NMBA.

238. The May 2017 inspection also found that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and there were black metallic particles in API batches.

239. The FDA inspector "noted reoccurring complaints pertained to particulate matter in API . . . and for discrepancies in testing between [ZHP] and their consignees. . . . . To address the firm's handling of complaints describing testing disparities, [the inspector] had the firm generate a list of such complaints, as well as associated pie charts . . . . From 2015 until May 2017, 13 complaints related to discrepancies between [ZHP]'s test results and their consignees results. Of these complaints 85% had what the firm termed 'Customer has no subsequent feedback or treatment.' Specifically, this 85% was further broken down

[92] https://www.bloomberg.com/news/features/2019-01-30/chinese-heart-drug-valsartan-recall-shows-fda-inspection-limits.

into 3 categories: the batch subject to the complaint was sent to other consignees who did not report a complaint, there is a test method discrepancy and feedback was provided to the consignee without a response and the consignee failed to respond but continued to purchase API from [ZHP]."

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

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

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

243. On September 28, 2018, the FDA stopped allowing ZHP to deliver drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not

appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

244. After the recalls of ZHP's valsartan-containing drugs, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at its Linhai City facilities contained NDMA levels hundreds of times in excess of the FDA's interim limits[93] of 96 ng/day or 0.3 ppm.[94] Specifically, valsartan-containing drugs manufactured at ZHP for ZHP's subsidiary Prinston Pharmaceutical contained NDMA levels of between 15,180 and 16,300 ng, while Valsartan HCT manufactured at ZHP contained NDMA levels of between 13,180 and 20,190 ng.[95]

245. In addition, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by ZHP at ZHP's Linhai City facilities for Torrent Pharmaceuticals contained NDEA levels upwards of fifty times in excess of the FDA's interim limits of 26.5 ng/day or 0.083 ppm. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent Pharmaceuticals' ICDs. ZHP valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng).

246. ZHP's irbesartan (sold through Sandoz, Inc. and Prinston Pharmaceutical d/b/a Solco Healthcare US LLC, respectively) was also recalled for containing nitrosamine levels which rose above the FDA's acceptable limit.

247. By the time ZHP and its associated Defendants announced limited recalls of irbesartan, ZHP had already been placed on import alert.

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[93] To be clear, ZHP's irbesartan products should not contain any NDMA.
[94] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed June 5, 2019).
[95] *Id.*

248. Plaintiffs allege upon information and belief that more than] and one lot of irbesartan were contaminated with nitrosamines, and yet to date, more than a year after the announcement of these initial recalls, ZHP, Sandoz, and Prinston have taken no additional action to release testing results or recall additional product.

ii. Aurobindo's Inadequate Manufacturing Processes

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

250. Aurobindo manufactures at least some of its ARB drugs at these facilities, and Aurobindo Defendants thus have quality assurance obligations with respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

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

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

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

production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Fourth, the "use of instruments and recording devices not meeting established specifications was observed."

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

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

256. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." Second,

"[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

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

258. In October 2018, the European Medicines Agency banned Aurobindo from selling irbesartan in the European Union, following recalls of some lots of the API made by Aurobindo.[96]

259. It is clear Aurobindo has made no efforts at correct any of the previously identified errors, and continues to engage in grossly inadequate manufacturing processes. During an inspection *one month ago this year* (May, 2019), an investigator made note of a panoply of serious issues which called the integrity of the API manufacturing operations into question.

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

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

262. The investigator also found a slew of data integrity issues. The investigator observed "multiple sequences where interrupted sample injections were injected and showed that the sample did not run, shown on the chromatogram as "incomplete data." The testing systems also allowed certain employees to "verify incomplete data in raw data file." The

[96] https://www.ema.europa.eu/en/news/eu-authorities-take-further-action-ongoing-review-sartans-zhejiang-huahai-placed-under-increased.

investigator found that the quality control reviewers attested to practices which "contradict actual review practices performed by reviews." Were these baseline data issues not enough, the investigator also noted that the facility did not retain adequate backup of the data.

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

264. On June 20, 2019, Aurobindo received yet another warning letter from the FDA which stemmed from FDA's inspection of one of Aurobindo's manufacturing facilities in India that took place from February 4-9, 2019.[97]

265. In this letter, FDA cited Aurobindo for "significant deviations" from cGMPs for active pharmaceutical ingredients and stated that its API was adulterated as a result of these deviations. The letter further stated that Aurobindo's contaminated API was due to the use of recovered solvents, and while Aurobindo had stopped using solvents from the particular vendor that provided them, Aurobindo had not solved other important quality issues. Aurobindo was further cited for violations stemming from its failure to report changes to its methods and procedures.

[97] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aurobindo-pharma-limited-577033-06202019.

266. After the recalls of Aurobindo's valsartan, FDA Laboratory Analysis testing would later reveal that valsartan API manufactured by Aurobindo contained NDEA exceedances well in excess of the FDA's interim limits[98] of 26.5 ng/day or 0.083 ppm.[99]

267. While testing results in the US for Autobindo's ICDs are not readily available, information released by Health Canada shows that numerous batches of Aurobindo's ICDs tested contained unsafe levels of NDEA as high as 30.29 nanograms per tablet[100], which exceeded the FDA's interim limit of 26.5 nanograms per day,

VIII. WARRANTIES COMMON TO ALL MANUFACTURER DEFENDANTS

268. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[101] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic ICDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic ICDs was bioequivalent to their RLDs.

269. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book,

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[98] To be clear, Aurobindo's irbesartan products should not contain any NDEA.

[99] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed June 5, 2019).

[100] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html.

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

therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

270. Each Defendant's ICDs is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved ICD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers like Plaintiffs of the "sameness" of their products to the ICD's RLD, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

271. By introducing their respective ICDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to physicians and patients like Plaintiffs that their ICDs are in fact the same as and are therapeutically interchangeable with their RLDs.

272. In addition, each Defendant affirmatively misrepresented and warranted to physicians and patients like Plaintiffs through their websites, brochures, and other marketing or informational materials that their ICDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

273. The presence of nitrosamines in Defendants' ICDs: (1) renders Defendants' ICDs non-bioequivalent (*i.e.*, not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' ICDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' ICDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and

express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, or negligently failed to ensure their ICDs' labels and other advertising or marketing statements accurately conveyed information about their products.

274. At all relevant times, Defendants have also impliedly warranted that their ICDs were merchantable and fit for their ordinary purposes.

275. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA, NDEA, NMBA, and other nitrosamines are not FDA-approved ingredients in ICDs. The presence of NDMA and other similar nitrosamines or impurities in Defendants' ICDs means that Defendants violated implied warranties to Plaintiffs and their physicians. The presence of NDMA, NDEA, or NMBA in Defendants' ICDs results in Defendants' ICDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

276. For these and other reasons, Defendants' ICDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such ICDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

277. Reasonable alternative designs to these contaminated ICDs were available, and Defendants should and could have manufactured actual generic irbesartan. This is especially so given that alternative, actual ICDs or competing medications with the same approved indications were available from other manufacturers.

A. ZHP Defendants' Warranties

278. On its January 29, 2019 website,[102] ZHP stated that it "has established an independent, strict and sound quality mangement [sic] system in accordance with GMP." ZHP further claims that it "ensure[s] that production is operated in accordance with GMP and product quality meets the required specifications," and that ZHP's "workshops of formulation are designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."

279. Huahai US assisted Prinston in obtaining approval of its ANDA for its ARB drugs.

280. Solco lists its ICDs as equivalent to Avapro and Avalide on its website.[103]

281. Furthermore, Solco states on the "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[104]

282. On the "Drug Safety" page of its website, Solco states that "Solco Healthcare is committed in providing . . . its patients with high quality, FDA-approved generic medications."[105]

B. Aurobindo Defendants' Warranties

283. Aurobindo's website states that it is "Committed to Quality and Safety."[106]

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[102] ZHP completely changed its website sometime in February or March 2019.
[103] https://www.solcohealthcare.com/shop/products/page/4/.
[104] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last accessed Apr. 5, 2019).
[105] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Apr. 5, 2019).
[106] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited June 5, 2019).

284. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[107] Aurobindo also "[s]eek[s] to attain the highest quality standards."[108]

285. Aurolife states, "The Aurolife family consists of an experienced management team with expertise in manufacturing, R&D, Quality Assurance and Quality control, finance and regulatory affairs. Aurolife has 100,000 square feet state-of-the-art US FDA approved cGMP compliant manufacturing facility with an investment of over US $50 million."[109]

C. ScieGen Pharmaceuticals Inc.'s Warranties

286. ScieGen's website lists its irbesartan tablets as the generic equivalent to Avapro.[110]

287. On its website, ScieGen states, "Our core business is in the areas of Development, Manufacturing, Marketing and Distribution of high quality and cost effective generic pharmaceutical products. ScieGen has robust product development pipeline and filed a couple of ANDA's. We aim to provide healthcare at economical prices to make this a healthier world to live in."[111]

D. Westminster Pharmaceuticals' Warranties

217. On its website, Westminster Pharmaceuticals warrants that it "provides high-quality and cost effective generic pharmaceuticals…"[112]

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[107] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last accessed June 5, 2019).
[108] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last accessed June 5, 2019).
[109] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last accessed June 5, 2019).
[110] https://sciegenpharm.com/products/.
[111] https://sciegenpharm.com/about-us/.
[112] https://www.wprx.com/about

218. The company's website further states, "We believe in access to high quality pharmaceuticals at affordable prices. Compliance is key. We don't cut corners, but rather have an effective methodology that allows us to acquire high-quality generic drugs within high-demand categories. Cut costs and offer your patients the best generic pharmaceuticals when you partner with Westminster."[113]

E. Golden State Medical Supply's Warranties

219. Golden State Medical Supply (GSMS, Inc.) warrants to its customers as follows: "We are a pharmaceutical company that specializes in delivering high-quality affordable generics and unique packaging solutions for our customers. A foundation of core values, including innovation, integrity and quality have lead to the rapid growth of our company. We strive to make every day better than the last, valuing that our products and our services impact millions of lives."[114]

220. The company further states on its website, "GSMS is dedicated to ensuring the integrity of not only our products but also the integrity of the pharmaceutical supply chain. We have the capabilities to meet the safety, packaging, labeling, serialization, and distribution needs of our customers and the patients they serve."[115]

IX. WARRANTIES COMMON TO ALL RETAIL PHARMACY DEFENDANTS

288. By selling drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments from consumers and TPPs are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics.

[113] https://www.wprx.com/retail-specialty-hospital-pharmacies.
[114] https://gsms.us/about-us/.
[115] https://gsms.us/about-us/.

289. Each Retail Pharmacy Defendants also supplied package inserts to Plaintiffs, which warranted that the drugs Plaintiffs received contained only the active ingredients on the label

290. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

X. WHOLESALE DISTRIBUTOR DEFENDANTS' WARRANTIES

291. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

292. Each Wholesale Distributor Defendants sold generic drugs as bioequivalents to the Brand Name drug.

XI. REPACKAGER AND RELABELER DEFENDANTS' WARRANTIES

293. By selling drugs in the stream of commerce and placing their own brands and label on the product, each repackager and relabeler defendant warrants that the generic drugs they sell are same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics.

294. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

XII. NEW REVELATIONS CONTINUE TO UNFOLD ABOUT OTHER MANUFACTURING PLANTS

295. The recalls of ARB drugs triggered a wave of investigations into the purity of drugs in the United States. Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known.

PLAINTIFFS' INJURIES

296. Plaintiffs and the Class were prescribed generic irbesartan during the time in which Defendants' ICDs were contaminated with NDMA, NDEA, NMBA, or other nitrosamines.

297. The ICDs purchased and/ or ingested by Plaintiffs and the Class were designed, manufactured, marketed, sold, and/or distributed by the above-captioned defendants, though the drugs turned out not to be generic irbesartan, but instead adulterated, misbranded, unapproved, and unregulated, ICDs containing dangerous levels of nitrosamines.

298. As a result of Plaintiffs' and the Class' purchase and/ or ingestion of the ICDs, Plaintiffs have greater exposure to an increased risk of cancers or development of cancers, which cause permanent and disabling injuries and/or death.

I. CAUSATION

299. Plaintiffs and the Class would not have consented to purchasing or taking the ICDs at issue, had Plaintiffs and the Class known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs, which were rendered unreasonably dangerous by the presence of NDMA, NDEA, MNBA and/or other nitrosamines.

300. Plaintiffs, the Class and Plaintiffs' physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of the ICDs.

301. Plaintiffs, the Class and Plaintiffs' physicians did not know of the specific increased risks and serious dangers, and/or were misled by Defendants, who knew or should have known of the true risks and dangers, but consciously chose not to inform Plaintiffs or

Plaintiffs' physicians of those risks and further chose to actively misrepresent those risks and dangers to the Plaintiffs and Plaintiffs' physicians.

302. Plaintiffs, the Class and Plaintiffs' physicians chose to take and prescribe the ICDs based on the risks and benefits disclosed to them by Defendants but would have made a difference choice, had the true risks and benefits been provided.

II. PLAINTIFFS' RESULTING DAMAGES AND INJURIES

303. Plaintiffs and the Class suffered damage as a direct and proximate result of the Defendants' failure to provide adequate warnings, failure to design, manufacture, sell, or distribute a safe product, and failure to adhere to safe manufacturing processes.

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

304. Plaintiffs and the Class had no reason until recently to suspect that their exposure to an increased risk of cancer was caused by Defendants' defective and unreasonably dangerous drug. Plaintiffs did not know and could not have known through the exercise of reasonable diligence that the use of contaminated ICDs caused Plaintiffs' injuries (or that Plaintiffs' ICDs were contaminated at all). For these reasons, Plaintiffs' Complaints were filed within the time period allowed by the applicable statutes of limitations.

305. Plaintiffs herein bring these actions within the applicable statutes of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' injuries and/or death and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know nor had reason to know of their injuries and/or the wrongful cause thereof.

306. Defendants' failure to document or follow up on the known defects of its products, and processes, and concealment of known defects, serious increased risks, dangers, and complications, constitutes fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein.

307. Defendants named herein are estopped from relying on any statute of limitations defense because they continue to downplay and deny reports and studies questioning the safety of their ICDs, actively and intentionally concealed the defects, suppressed reports and adverse information, failed to satisfy FDA and other regulatory and legal requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and Plaintiffs.

308. Defendants performed the above acts, which were and are illegal, to encourage physicians and patients to prescribe and take ICDs in their contaminated and unreasonably dangerous forms.

309. At all relevant times, the Defendants were under a continuing duty to disclose the true character, quality, and nature of the increased risks and dangers associated with ICDs, particularly when the drugs ceased to be the same as its brand-name counterpart.

310. Defendants furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in ICDs, and a continued and systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

311. Defendants' acts and omissions, before, during and/or after the act causing Plaintiffs' injuries, prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injury or causes thereof until recently.

312. Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of Plaintiffs and other patients.

GENERAL ALLEGATIONS

313. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

314. At all relevant times, the ICDs purchased and/or ingested by Plaintiffs were researched, developed, manufactured, marketed, promoted, packaged, labeled, advertised, sold, designed and/or distributed by Defendants.

315. Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold, packaged, labeled, designed and/or distributed the ICDs purchased and/or ingested by Plaintiffs as safe and effective treatment for Plaintiffs' underlying conditions.

316. Defendants knew, and/or had reason to know, that the ICDs purchased and/or ingested by Plaintiffs were defective, unreasonably dangerous, and not safe for the purposes and uses that these Defendants intended.

317. Defendants knew, and/or had reason to know, that the ICDs purchased and/or ingested by Plaintiffs were defective, unreasonably dangerous and not safe for human consumption, as they contained dangerously high levels of carcinogenic compounds, namely NDMA, NDEA, NMBA, and other nitrosamines.

I. REPRESENTATIONS

318. Defendants (in the roles described herein) designed, manufactured, labeled, marketed, packaged, distributed, and promoted the ICDs purchased and/or ingested by Plaintiffs for treatment of high blood pressure and other indications.

319. Defendants misrepresented, downplayed, and/or omitted the safety risks of the ICDs purchased and/or ingested by Plaintiffs to physicians and patients, including Plaintiffs and

Plaintiffs' physicians by failing to identify, test for, and disclose the presence of nitrosamines in their products and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

320. Defendants failed to warn and/or alert physicians and patients, including Plaintiffs and Plaintiffs' physicians, of the increased risks and significant dangers resulting from the FDA-unapproved use of the ICDs purchased and/or ingested by Plaintiffs, which contained carcinogenic compounds.

321. Defendants knew and/or should have known that their representations and suggestions to physicians that their ICDs were safe and effective for such uses, were materially false and misleading and that physicians and patients including Plaintiffs and Plaintiffs' physicians, would rely on such representations.

322. Defendants failed to conduct proper testing relating to the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiffs and Plaintiffs' physicians.

323. Defendants failed to seek FDA approval for the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiffs and Plaintiffs' physicians.

324. Defendants failed to sufficiently conduct post-market surveillance for the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiffs and Plaintiffs' physicians.

325. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest level of Defendants, including the corporate officers.

326. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the use of the ICDs purchased and/or ingested by Plaintiff, but they concealed this information and did not warn Plaintiffs or Plaintiffs' physicians, preventing Plaintiff

and Plaintiffs' physicians from making informed choices in selecting other treatments or therapies and preventing Plaintiffs and Plaintiffs' physicians from timely discovering Plaintiffs' injuries.

327. Defendants knew or should have known that the manufacturing processes employed to make the irbesartan-containing drugs purchased and/or ingested by Plaintiffs were unreasonably dangerous, unsafe, unvalidated, and not properly studied or tested.

328. Defendants knew or should have known that it is the duty of all entities in the chain of manufacture and distribution to test its products to ensure they meet quality and safety standards. Yet, Defendants failed to do so.

329. Had Defendants performed adequate tests on the ICDs, these defendants would have discovered that these drugs were not safe for human consumption.

ADDITIONAL ALLEGATIONS RELATING TO PUNITIVE DAMAGES

330. The Manufacturer, Labeler, and Repackager Defendants are under an obligation to ensure that their drugs, which were supposed to be biological equivalents to their brand name counterparts, were exactly that.

331. The Manufacturer Defendants failed to conduct proper quality control on their manufacturing processes, such that the product they produced resulted in an entirely new and unapproved drug with undisclosed active ingredients, namely NDMA NDEA, NMBA, and/or other nitrosamines.

332. The non-Manufacturer Defendants failed to conduct proper due diligence on the drugs and the manufacturers, their processes, quality control, and facilities before purchasing, wholesaling, distributing, repackaging, relabeling, and selling the drugs.

333. Defendants further failed to conduct adequate testing of their product once it had been manufactured, distributed, and/or sold.

334. Defendants further failed to conduct adequate post-market surveillance.

335. NDMA, NDEA, NMBA, and other closely related nitrosamines have been known carcinogens for years.

336. Defendants failed to adequately test the product they were manufacturing, marketing, distributing, repackaging, and selling to doctors and patients, like Plaintiffs and Plaintiffs' physicians. This inadequate testing went on for years, such that pills containing unreasonably dangerous and carcinogenic substances were distributed to millions of American consumers, as well as consumers throughout the world.

337. In marketing and selling these drugs, Defendants provided false and misleading labels to physicians and patients, including to Plaintiffs and Plaintiffs' physicians, which failed to disclose that the drug being prescribed to and ingested by Plaintiffs was not irbesartan, but an entirely new, unapproved, misbranded, adulterated, and dangerous drug.

338. As a result of Defendants' failure to disclose the ingredients of these drugs, their failure to conduct proper testing, their failure to have adequate quality control measures in place, as well as other actions mentioned in this Complaint, Defendants made millions of dollars. This all occurred while Defendants were cutting manufacturing costs by reusing solvents in the manufacturing process.

339. As a result of Defendants' deliberate disregard for the safety of American consumers, including Plaintiff, Plaintiff, as well as many other Americans, developed cancer.

340. As a legal and proximate result of Defendants' misconduct, callous disregard, and omissions, as herein alleged, Plaintiffs sustained the injuries, damages, and losses set forth above.

341. Defendants' conduct and omissions, as set forth above, in allowing such an extremely dangerous products to be used by members of the general public, including Plaintiffs, constitutes fraud, malice, and oppression toward Plaintiffs and others.

342. Plaintiffs are therefore entitled to exemplary or punitive damages, which would serve to punish the Defendants, to deter wrongful conduct, to encourage safer products are made in the future, and to ensure Defendants adhere to safe manufacturing practices.

343. Plaintiff is therefore entitled to judgment against Defendants as hereinafter set forth.

CLASS ACTION ALLEGATIONS

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

> All individuals and entities in the United States and its territories and possessions who, since at least January 1, 2011 to the present, paid any amount of money for a irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.

345. The Nationwide Class has two sub-classes:

> All consumers in the United States and its territories and possessions who, since at least January 1, 2011 to the present, paid any amount of money for a irbesartan-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, since at least January 1, 2011 to the present, paid any amount of money for a irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant.

346. 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, since at least January 1, 2011 to the present, paid any amount of money out of pocket for a irbesartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant. These include but are not limited to the following:

a. Plaintiffs Bacharach and Annis seek to represent a Florida sub-class and/or subclass(es) of states with similar applicable laws to Florida.

b. Plaintiff Wineinger seeks to represent an Indiana sub-class and/or subclass(es) of states with similar applicable laws to Indiana.

c. Plaintiff Johnson seeks to represent a New York sub-class and/or subclass(es) of states with similar applicable laws to New York.

d. Plaintiff Miller seeks to represent a Maryland sub-class and/or subclass(es) of states with similar applicable laws to Maryland.

e. Plaintiff Westry seeks to represent an Alabama sub-class and/or subclass(es) of states with similar applicable laws to Alabama.

f. Plaintiffs reserve the right to amend this Complaint to add additional class representatives as appropriate or necessary for additional sub-classes for one or more states

347. Collectively, the foregoing Nationwide Class and its sub-classes are referred to as the "Class."

348. 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.

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

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

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

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

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

b. Whether each Defendant's ICDs were in fact the same as their RLDs consistent with such express or implied warranties;

c. Whether each Defendant's ICDs were contaminated with NDMA, NDEA, or similar contaminants;

d. Whether each Defendant's ICDs containing NMDA, NDEA, or similar contaminants were adulterated and/or misbranded;

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

f. Whether each Defendant falsely claimed that its ICDs were the same as their RLDs and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

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

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

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

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

353. **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.

354. **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.

355. 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.

356. The requirements of Rule 23(b)(3) are met. The common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues 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 CAUSE OF ACTION
I. NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

357. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

359. Defendants marketed these drugs to and for the benefit of Plaintiffs and the Class.

360. Defendants owed Plaintiffs, the Class, and Plaintiffs' physicians, duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing scientific knowledge at the time the products were sold.

361. Through the conduct described in this Complaint, Defendants breached their duties to Plaintiffs and the Class and to their physicians.

362. Specifically, Defendants manufactured, marketed, sold, packaged, labeled, and/or distributed misbranded and adulterated products to Plaintiffs, the Class and their physicians that they knew or should have known contained unacceptable and dangerous levels of nitrosamines.

363. Defendants further manufactured, marketed, sold, packaged, labeled, and/or distributed unapproved and unsafe drugs to Plaintiffs, the Class and their physicians.

364. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiffs, the Class and their physicians would purchase and/or use and did purchase and/ or use their products to their detriment.

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

SECOND CAUSE OF ACTION
II. NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

366. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

367. 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.

368. Defendants marketed these drugs to and for the benefit of Plaintiffs and the Class.

369. Defendants owed Plaintiffs, the Class, and their physicians, duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing scientific knowledge at the time the products were sold.

370. Through the conduct described in this Complaint, Defendants breached their duties to Plaintiffs and the Class and to their physicians.

371. Specifically, Defendants manufactured, marketed, sold, packaged, labeled, and/or distributed misbranded and adulterated products to Plaintiffs, the Class and their physicians that they knew or should have known contained unacceptable and dangerous levels of nitrosamines.

372. Defendants further manufactured, marketed, sold, packaged, labeled, and/or distributed unapproved and unsafe drugs to Plaintiffs, the Class and their physicians.

373. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiffs and the Class and their physicians would purchase and/or use and did purchase and/or use their products to the detriment.

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

THIRD CAUSE OF ACTION

III. **NEGLIGENCE PER SE**

375. (INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

376. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

378. Defendants violated federal statutes and regulations, including but not limited to the statutes cited herein.

379. The ICDs purchased and/or ingested by Plaintiffs and the Class were designed, manufactured, sold, and distributed in violation of federal and state common law, as these drugs never received FDA approval before being marketed and sold to Plaintiffs' physician, Plaintiffs and the Class.

380. The ICDs purchased and/or ingested by Plaintiffs and the Class were adulterated and misbranded in that they were contaminated with unsafe levels of highly carcinogenic nitrosamines. These same actions which rendered the drugs adulterated and misbranded under federal law similarly rendered the drugs unsafe under applicable state tort laws, and violation of these safety standards constitutes negligence per se.

381. Defendants' actions, which constitute violations of the federal laws mentioned in this Complaint, simultaneously violated common law obligations. Plaintiffs' and the Class' state-law claims do not impose any additional requirements on Defendants, beyond what is already required under federal law.

382. Defendants had a duty to comply with the applicable regulations. Notwithstanding this duty, Defendants breached this duty by designing, manufacturing, labeling, distributing, marketing, advertising, and promoting the unapproved and unreasonably dangerous ICDs to Plaintiffs, the Class and their physicians.

383. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiffs' physicians prescribed, and Plaintiffs and the Class purchased and/or ingested these drugs, which were unreasonably dangerous.

384. Defendants failed to act as reasonably prudent drug designers, manufacturers, wholesalers, distributers, marketers, and sellers should.

385. 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.

386. Plaintiffs and the Class are not seeking to enforce these federal provisions in this action. Likewise, Plaintiffs and the Class are not suing merely because Defendants' conduct violates these provisions. Rather Plaintiffs and the Class alleges that Defendants' conduct that violates these provisions also violates state laws, which do not impose any obligations beyond those already required under federal law.

387. Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence per se in tort under state common law.

388. Thus, for violation of federal law, including the CGMP and FDCA and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, there already exists a money damages remedy under state common law.

389. Defendants' violations of these federal statutes and regulations caused Plaintiffs and the Class' injuries.

390. Plaintiffs and the Class' injuries resulted from an occurrence that these laws and regulations were designed to prevent.

391. Plaintiffs and the Class are persons whom these statutes and regulations were meant to protect.

392. Defendants' violation of these statutes or regulations constitutes negligence per se.

FOURTH CAUSE OF ACTION
IV. NEGLIGENCE PER SE

(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

393. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

394. 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.

395. Defendants violated federal statutes and regulations, including but not limited to the statutes cited herein.

396. The ICDs purchased and/or ingested by Plaintiffs and the Class were designed, manufactured, sold, and distributed in violation of federal and state common law, as these drugs never received FDA approval before being marketed and sold to Plaintiffs' physician, Plaintiffs and the Class.

397. The ICDs purchased and/or ingested by Plaintiffs and the Class were adulterated and misbranded in that they were contaminated with unsafe levels of highly carcinogenic nitrosamines. These same actions which rendered the drugs adulterated and misbranded

under federal law similarly rendered the drugs unsafe under applicable state tort laws, and violation of these safety standards constitutes negligence per se.

398. Defendants' actions, which constitute violations of the federal laws mentioned in this Complaint, simultaneously violated common law obligations. Plaintiffs' and the Class' state-law claims do not impose any additional requirements on Defendants, beyond what is already required under federal law.

399. Defendants had a duty to comply with the applicable regulations. Notwithstanding this duty, Defendants breached this duty by designing, manufacturing, labeling, distributing, marketing, advertising, and promoting the unapproved and unreasonably dangerous ICDs to Plaintiffs, the Class and their physicians.

400. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiffs' physicians prescribed, and Plaintiffs and the Class purchased and/or ingested these drugs, which were unreasonably dangerous.

401. Defendants failed to act as reasonably prudent drug designers, manufacturers, wholesalers, distributers, marketers, and sellers should.

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.

403. Plaintiffs and the Class are not seeking to enforce these federal provisions in this action. Likewise, Plaintiffs and the Class are not suing merely because Defendants' conduct violates these provisions. Rather Plaintiffs and the Class alleges that Defendants' conduct that violates these provisions also violates state laws, which do not impose any obligations beyond those already required under federal law.

404. Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence per se in tort under state common law.

405. Thus, for violation of federal law, including the CGMP and FDCA and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, there already exists a money damages remedy under state common law.

406. Defendants' violations of these federal statutes and regulations caused Plaintiffs and the Class' injuries.

407. Plaintiffs and the Class' injuries resulted from an occurrence that these laws and regulations were designed to prevent.

408. Plaintiffs and the Class are persons whom these statutes and regulations were meant to protect.

409. Defendants' violation of these statutes or regulations constitutes negligence per se.

410. FIFTH CAUSE OF ACTION

V. BREACH OF EXPRESS WARRANTY
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

411. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

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

413. 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. § 34.1-2313

414. Defendants utilized false and deceptive product labels and other labeling, as well as advertising to promote, encourage, and urge the use, purchase, and utilization of these drugs by representing the quality and safety to health care professionals, Plaintiffs, the Class, and the public in such a way as to induce their purchase or use. Defendants expressly represented and warranted that these drugs were compliant with cGMPs and not adulterated or contaminated.

415. Through these representations, Defendants made express warranties that these irbesartan-containing drugs would conform to the representations. U.C.C. § 2-313. More specifically, Defendants represented that these drugs, when ingested by Plaintiffs and the

Class in the manner foreseen by Defendants, were safe and effective, that these drugs were safe and effective for use by individuals such as Plaintiffs and the Class, and/or that these drugs were safe and effective to treat their conditions given the risk profile Defendants disclosed in their labeling and through their representations to Plaintiffs, the Class and their physicians.

416. Defendants represented that their drugs were sold in accordance with their ANDAs, were FDA-approved (which required complying with applicable cGMPS) and that these drugs only contained the active ingredients disclosed on the label. These specific misrepresentations went beyond mere puffery as they were printed on the very product and in the product labeling.

417. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

418. The drugs purchased by Plaintiffs and the Class did not conform to the representations made by Defendants, because these drugs were not safe for human ingestion in the manner intended by Defendants and contained active ingredients not disclosed in the product labeling.

419. At all relevant times, Plaintiffs and the Class purchased and/ or ingested these drugs for the purpose and in the manner intended by Defendants.

420. Plaintiffs, the Class and their physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its hidden increased risks and its unreasonable dangers.

421. Defendants breached their express warranties with respect to the drugs because they did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to branded ICDs, and could not lawfully be sold.

422. Defendants' breaches constitute violations of state common laws.

423. 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 ICDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

SIXTH CAUSE OF ACTION
VI. BREACH OF EXPRESS WARRANTY
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

424. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

425. 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.

426. 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. § 34.1-2313

427. Defendants utilized false and deceptive product labels and other labeling, as well as advertising to promote, encourage, and urge the use, purchase, and utilization of these drugs by representing the quality and safety to health care professionals, Plaintiffs, the Class, and the public in such a way as to induce their purchase or use. Defendants expressly represented and warranted that these drugs were compliant with cGMPs and not adulterated or contaminated.

428. Through these representations, Defendants made express warranties that these irbesartan-containing drugs would conform to the representations. U.C.C. § 2-313. More specifically, Defendants represented that these drugs, when ingested by Plaintiffs and the

Class in the manner foreseen by Defendants, were safe and effective, that these drugs were safe and effective for use by individuals such as Plaintiffs and the Class, and/or that these drugs were safe and effective to treat their conditions given the risk profile Defendants disclosed in their labeling and through their representations to Plaintiffs, the Class and their physicians.

429. Defendants represented that their drugs were sold in accordance with their ANDAs, were FDA-approved (which required complying with applicable cGMPS) and that these drugs only contained the active ingredients disclosed on the label. These specific misrepresentations went beyond mere puffery as they were printed on the very product and in the product labeling.

430. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

431. The drugs purchased by Plaintiffs and the Class did not conform to the representations made by Defendants, because these drugs were not safe for human ingestion in the manner intended by Defendants and contained active ingredients not disclosed in the product labeling.

432. At all relevant times, Plaintiffs and the Class purchased and/ or ingested these drugs for the purpose and in the manner intended by Defendants.

433. Plaintiffs, the Class and their physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its hidden increased risks and its unreasonable dangers.

434. Defendants breached their express warranties with respect to the drugs because they did not comply with cGMPs, were adulterated and contaminated, were not bioequivalent to branded ICDs, and could not lawfully be sold.

435. Defendants' breaches constitute violations of state common laws.

436. 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 ICDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

SEVENTH CAUSE OF ACTION
VII. BREACH OF IMPLIED WARRANTY
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

437. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

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

439. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp.

Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2314; 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. § 552-314; 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 § 2314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

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

441. ICDs are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

442. Defendants were obligated to provide Plaintiffs and the other Class Members reasonably fit ICDs that were of merchantable quality, were reasonably fit for the purpose for which they were sold and conformed to the standards of the trade in which Defendants are involved, such that the drugs were of fit and merchantable quality.

443. Defendants knew, had reason to know, and should have known that the drugs were being manufactured and sold for the intended purpose of human consumption as a safe

alternative to, and the bioequivalent of, branded ICDs, and impliedly warranted that those drugs were of merchantable quality and fit for that purpose.

444. The ICDs were not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were these products minimally safe for their expected purpose.

445. At all relevant times, Plaintiffs and the Class purchased and/or used these products for the purpose and in the manner intended by Defendants.

446. The breach of the warranty was a substantial factor in bringing about Plaintiffs and the Class' injuries.

447. Defendants breached their implied warranty to Plaintiffs and the Class in that Defendants' products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of state common law principles.

448. 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' ICDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

EIGHTH CAUSE OF ACTION
VIII. BREACH OF IMPLIED WARRANTY
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

449. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

450. 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.

451. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2314; 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. § 552-314; 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 § 2314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

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

453. ICDs are and were "goods" within the meaning of Article 2 of the U.C.C., as codified under applicable law.

454. Defendants were obligated to provide Plaintiffs and the other Class Members reasonably fit ICDs that were of merchantable quality, were reasonably fit for the purpose for which they were sold and conformed to the standards of the trade in which Defendants are involved, such that the drugs were of fit and merchantable quality.

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

456. The ICDs were not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were these products minimally safe for their expected purpose.

457. At all relevant times, Plaintiffs and the Class purchased and/or used these products for the purpose and in the manner intended by Defendants.

458. The breach of the warranty was a substantial factor in bringing about Plaintiffs and the Class' injuries.

459. Defendants breached their implied warranty to Plaintiffs and the Class in that Defendants' products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of state common law principles.

460. 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' ICDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

NINTH CAUSE OF ACTION
IX. MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

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

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

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

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

465. Each Defendant expressly or impliedly warranted their ICDs as alleged in this Complaint.

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

467. No Defendant has acted on the opportunity to cure its failure with respected to its warranted ICDs.

468. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

TENTH CAUSE OF ACTION
X. MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, ET SEQ.
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

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

470. 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.

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

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

473. Each Defendant expressly or impliedly warranted their ICDs as alleged in this Complaint.

474. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service

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

475. No Defendant has acted on the opportunity to cure its failure with respected to its warranted ICDs.

476. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

ELEVENTH CAUSE OF ACTION
XI. FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)

(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

477. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

479. These Defendants had a confidential and special relationship with Plaintiffs and the Class and/or their physicians due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to their drugs; and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting these unapproved, carcinogenic drugs.

480. Upon information and belief, Defendants were aware that their drugs contained dangerous and carcinogenic compounds, namely NDMA, NDEA, NMBA and/or other nitrosamines.

481. Defendants had an affirmative duty to fully and adequately warn Plaintiffs, the Class and their physicians of the true health and safety risks associated with these drugs for the uses intended by these Defendants; namely, that these drugs contained unsafe levels of NDMA, NDEA, NMBA, and/or other nitrosamines.

482. Defendants also had a duty to disclose their dangerous and irresponsible practices of improperly designing, manufacturing, selling, marketing, and distributing drugs that did not have FDA approval and drugs which had not been sufficiently studied.

483. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the risks associated with using their ICDs from Plaintiffs, the Class and/or their physicians. Instead, under state common law, these Defendants had a duty to fully disclose such risks and dangers to Plaintiffs, the Class and/or their physicians.

484. Defendants fraudulently and intentionally misrepresented and/or fraudulently concealed material and important health and safety product risk information from Plaintiffs, the Class and their physicians, as alleged in this Complaint.

485. Plaintiffs, the Class and/or Plaintiffs' physicians would not have decided to prescribe and purchase these drugs had they known of the true safety risks related to such use, all of which were known to Defendants.

486. Defendants knew that they were concealing and/or misrepresenting true information about the comparative risks and benefits of the irbesartan-containing drugs and the relative benefits and availability of alternate products, treatments and/or therapies.

487. Defendants knew that Plaintiffs, the Class and their physicians would regard the matters Defendants concealed and/or misrepresented to be important in determining the course of treatment for Plaintiffs, including Plaintiffs, the Class and their physicians'

decisions regarding whether to prescribe and ingest the ICDs for the purposes and in the manner intended by these Defendants.

488. Defendants intended to cause Plaintiffs, the Class and their physicians to rely on their concealment of information and/or misrepresentations about the safety risks related to these drugs to induce them to prescribe and ingest the drugs.

489. Plaintiffs, the Class and/or their physicians were justified in relying, and did rely, on Defendants' concealment of information and/or misrepresentations about the safety risks related to the ICDs in deciding to prescribe and purchase these drugs.

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

TWELTH CAUSE OF ACTION
XII. FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)

(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

491. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

492. 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.

493. These Defendants had a confidential and special relationship with Plaintiffs and the Class and/or their physicians due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to their drugs; and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting these unapproved, carcinogenic drugs.

494. Upon information and belief, Defendants were aware that their drugs contained dangerous and carcinogenic compounds, namely NDMA, NDEA, NMBA and/or other nitrosamines.

495. Defendants had an affirmative duty to fully and adequately warn Plaintiffs, the Class and their physicians of the true health and safety risks associated with these drugs for the uses intended by these Defendants; namely, that these drugs contained unsafe levels of NDMA, NDEA, NMBA, and/or other nitrosamines.

496. Defendants also had a duty to disclose their dangerous and irresponsible practices of improperly designing, manufacturing, selling, marketing, and distributing drugs that did not have FDA approval and drugs which had not been sufficiently studied.

497. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the risks associated with using their ICDs from Plaintiffs, the Class and/or their physicians. Instead, under state common law, these Defendants had a duty to fully disclose such risks and dangers to Plaintiffs, the Class and/or their physicians.

498. Defendants fraudulently and intentionally misrepresented and/or fraudulently concealed material and important health and safety product risk information from Plaintiffs, the Class and their physicians, as alleged in this Complaint.

499. Plaintiffs, the Class and/or Plaintiffs' physicians would not have decided to prescribe and purchase these drugs had they known of the true safety risks related to such use, all of which were known to Defendants.

500. Defendants knew that they were concealing and/or misrepresenting true information about the comparative risks and benefits of the irbesartan-containing drugs and the relative benefits and availability of alternate products, treatments and/or therapies.

501. Defendants knew that Plaintiffs, the Class and their physicians would regard the matters Defendants concealed and/or misrepresented to be important in determining the course of treatment for Plaintiffs, including Plaintiffs, the Class and their physicians' decisions regarding whether to prescribe and ingest the ICDs for the purposes and in the manner intended by these Defendants.

502. Defendants intended to cause Plaintiffs, the Class and their physicians to rely on their concealment of information and/or misrepresentations about the safety risks related to these drugs to induce them to prescribe and ingest the drugs.

503. Plaintiffs, the Class and/or their physicians were justified in relying, and did rely, on Defendants' concealment of information and/or misrepresentations about the safety risks related to the ICDs in deciding to prescribe and purchase these drugs.

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

THIRTEENTH CAUSE OF ACTION

XIII. NEGLIGENT MISREPRESENTATION AND OMISSION

(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

505. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

507. At all relevant times, Defendants were engaged in the business of manufacturing, marketing, distributing, and selling the ICDs for resale or use, and in fact did sell these drugs to Plaintiffs and the Class.

508. Specific defects in these products, as specified above in this Complaint, rendered them defective and unreasonably dangerous.

509. In the course of marketing these products, the Defendants made untrue representations of material facts and/or omitted material information to Plaintiffs, the Class, Plaintiffs' physicians, and the public at large.

510. Plaintiffs, the Class and/or their physicians reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase these products.

511. Plaintiffs, the Class and Plaintiffs' physicians would not have purchased and used these products had they known of the true safety risks related to such use.

512. Defendants were negligent in making these untrue misrepresentations and/or omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their products.

513. Plaintiffs, the Class and their physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Defendants' products.

514. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

FOURTEENTH CAUSE OF ACTION
XIV. NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

515. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

516. 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.

517. At all relevant times, Defendants were engaged in the business of manufacturing, marketing, distributing, and selling the ICDs for resale or use, and in fact did sell these drugs to Plaintiffs and the Class.

518. Specific defects in these products, as specified above in this Complaint, rendered them defective and unreasonably dangerous.

519. In the course of marketing these products, the Defendants made untrue representations of material facts and/or omitted material information to Plaintiffs, the Class, Plaintiffs' physicians, and the public at large.

520. Plaintiffs, the Class and/or their physicians reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase these products.

521. Plaintiffs, the Class and Plaintiffs' physicians would not have purchased and used these products had they known of the true safety risks related to such use.

522. Defendants were negligent in making these untrue misrepresentations and/or omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their products.

523. Plaintiffs, the Class and their physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Defendants' products.

524. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

FIFTEENTH CAUSE OF ACTION
XV. VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

525. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

527. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they failed to adequately warn consumers and the medical community of the safety risks associated with the irbesartan-containing drugs ingested by Plaintiffs and the Class and when they falsely marketed the drugs taken by Plaintiffs and the Class as generic versions and bio-equivalents.

528. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and the Class suffered damage.

529. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code 1975 § 8-19-1, et seq.

530. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471.

531. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. Ann. §§44-1521 et seq.

532. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. §§4-8-101 et seq.

533. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §§1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.

534. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §§6-1-105 et seq.

535. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. Ann. §§42-110a et seq.

536. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6 §§2511 et seq. and 2531 et seq.

537. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of D.C. Code Ann. §§28-3901 et seq.

538. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Stat. Ann. §501.201.

539. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §§10-1-372 and 10-1-420.

540. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §§480-1 et seq.

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

542. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Ill. Comp. Stat. 505/1 et seq.

543. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. 24-5-0.5-3.

544. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.16.

545. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. Ann. §§50-623 et seq.

546. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. Ann. §367.170.

547. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of LRA-RS 51:1401, et seq.

548. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Me. Rev. Sta. Ann. tit. 5, §§205-A et seq.

549. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Code Ann., Com. Law §§13-301 et seq.

550. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ge. Laws ch. 93A, §§I et seq.

551. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. §§445.901 et seq.

552. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of. Minn. State. §325D.44(13) et. seq. and Minn. Stat. §325F.67 621.

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

554. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Ann. Stat. §§407.010 et seq.

555. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Aim. §§30-14-101 et seq.

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

557. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. §§598.0903 et seq.

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

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

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

561. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§349 et seq. and 350-e et seq.

562. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §§75-1 et seq.

563. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§51-12-01 et seq. and 51- 15-01 et seq.

564. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Code Ann. §§1345.01 et seq.

565. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representation in violation of Okla. Stat. Ann. tit. 15, §§751 et seq.

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

567. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Cons. Stat. §§201-1 et seq.

568. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§6-13.1-1 et seq.

569. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Ann. §§39-5-10 et seq.

570. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§37-24-1 et seq.

571. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. §47-18-109(a)(l).

572. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 et seq.

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

574. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §§2453 et seq.

575. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. §§59.1-196 et seq.

576. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code Ann. §§19.86.010 et seq.

577. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W.Va. Code 46A-6-101 et seq.

578. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. Ann. §100.18.

579. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. Ann. §§40-12-101 et seq.

580. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of Irbesartan-containing drugs and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

581. Plaintiffs, the Class and their physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe the ICDs.

582. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages.

583. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class suffered damage.

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

SIXTEENTH CAUSE OF ACTION

XVI. VIOLATION OF STATE CONSUMER PROTECTION LAWS

(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

585. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

586. 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.

587. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they failed to adequately warn consumers and the medical community of the safety risks associated with the irbesartan-containing drugs ingested by Plaintiffs and the Class and when they falsely marketed the drugs taken by Plaintiffs and the Class as generic versions and bio-equivalents.

588. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and the Class suffered damage.

589. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code 1975 § 8-19-1, et seq.

590. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471.

591. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. Ann. §§44-1521 et seq.

592. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. §§4-8-101 et seq.

593. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §§1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.

594. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §§6-1-105 et seq.

595. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. Ann. §§42-110a et seq.

596. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6 §§2511 et seq. and 2531 et seq.

597. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of D.C. Code Ann. §§28-3901 et seq.

598. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Stat. Ann. §501.201.

599. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §§10-1-372 and 10-1-420.

600. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §§480-1 et seq.

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

602. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Ill. Comp. Stat. 505/1 et seq.

603. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. 24-5-0.5-3.

604. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.16.

605. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. Ann. §§50-623 et seq.

606. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. Ann. §367.170.

607. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of LRA-RS 51:1401, et seq.

608. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Me. Rev. Sta. Ann. tit. 5, §§205-A et seq.

609. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Code Ann., Com. Law §§13-301 et seq.

610. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ge. Laws ch. 93A, §§I et seq.

611. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. §§445.901 et seq.

612. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of. Minn. State. §325D.44(13) et. seq. and Minn. Stat. §325F.67 621.

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

614. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Ann. Stat. §§407.010 et seq.

615. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Aim. §§30-14-101 et seq.

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

617. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. §§598.0903 et seq.

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

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

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

621. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§349 et seq. and 350-e et seq.

622. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §§75-1 et seq.

623. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§51-12-01 et seq. and 51- 15-01 et seq.

624. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Code Ann. §§1345.01 et seq.

625. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representation in violation of Okla. Stat. Ann. tit. 15, §§751 et seq.

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

627. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Cons. Stat. §§201-1 et seq.

628. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§6-13.1-1 et seq.

629. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Ann. §§39-5-10 et seq.

630. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§37-24-1 et seq.

631. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. §47-18-109(a)(l).

632. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 et seq.

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

634. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §§2453 et seq.

635. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. §§59.1-196 et seq.

636. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code Ann. §§19.86.010 et seq.

637. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W.Va. Code 46A-6-101 et seq.

638. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. Ann. §100.18.

639. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. Ann. §§40-12-101 et seq.

640. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of

Irbesartan-containing drugs and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

641. Plaintiffs, the Class and their physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe the ICDs.

642. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages.

643. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class suffered damage.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

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

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

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

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

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

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

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

JURY DEMAND

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

Dated: 12/18/2020

Respectfully Submitted,

/s/ Ruben Honik
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MDL Plaintiffs' Co-Lead Counsel