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
This document relates to:	Honorable Robert B. Kugler, Honorable Joel Schneider,
All Cases	**Master Personal Injury Complaint**
	Jury Trial Demanded

TABLE OF CONTENTS

INTRODUCTION

1. 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.

2. Plaintiffs bring this Complaint as a result of Plaintiffs' development of cancers, as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

3. 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 valsartan-containing drugs ("VCDs"). 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 injuries incurred by Defendants' defective products.

4. This Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Master Complaint and the necessary causes of action herein through use of a separate Master Short Form Complaint, which will specify the particular products and defendants against whom claims are asserted by that individual plaintiff. Any separate facts and additional claims of individual plaintiffs are set forth in those actions filed by the respective plaintiffs.

5. This Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any Plaintiff relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each Plaintiff maintains that the VCDs they 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

6. Plaintiffs in these actions seek compensation for injuries and/or death resulting from use of defective prescription VCDs designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

7. The VCDs at issue in this litigation contained impurities, including, but not limited to, N-Nitroso-dimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), or other nitrosamine compounds.

8. This case arises from adulterated, misbranded, and unapproved valsartan-containing drugs ("VCDs") that were designed, manufactured, marketed, distributed, packaged, and sold by Defendants 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.

9. Valsartan and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Diovan® ("DIOVAN") and Diovan HCT® ("DIOVAN HCT"), respectively. Amlodipine-valsartan and its combination therapy with hydrochlorothizide are the generic versions of the RLDs of Exforge® ("EXFORGE") and Exforge HCT® ("EXFORGE HCT"), 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.

10. According to the Food and Drugs Administration ("FDA") testing, the generic VCDs at issue in this case contained 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 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").

11. The contamination of Defendants' VCDs 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.

12. Defendants have been illegally manufacturing, selling, labeling, and distributing adulterated generic VCDs in the United States since as far back as September 2012, when Defendant Mylan launched a DIOVAN HCT generic after its valsartan HCT Abbreviated New Drug Application ("ANDA") was approved by the FDA.

13. At all times during the period alleged herein Defendants represented and warranted to consumers and physicians that their generic VCDs 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.

14. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic VCDs were manufactured for import to the United States, and knowingly designed,

[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).

manufactured, marketed, sold, labeled, packaged, and/or distributed adulterated and misbranded VCDs to Plaintiffs and their prescribing physicians.

15. As a result of Defendants' actions, Plaintiffs suffered lasting and permanent injuries, including cancer and death.

PARTIES

I. PLAINTIFFS

16. This Master Complaint is filed on behalf of all Individual Injured Plaintiffs ("Plaintiffs") whose claims are subsumed within MDL No. 2875. Plaintiffs in these individual actions suffered personal injuries as a result of the use of VCDs. In addition, and where applicable, this Master Complaint is also filed on behalf of Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, all as represented by Plaintiffs' counsel.

17. Plaintiffs suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with, inter alia, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of their respective VCDs.

II. DEFENDANTS

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

19. Active Pharmaceutical Ingredient manufacturers ("API manufacturers") then sell to Finished Dose Manufacturers, who then sell the VCDs 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

20. Much of the VCDs 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.[2] Some of its VCDs also contained NDEA.[3]

i. Zhejiang Huahai Pharmaceutical Co., Ltd

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

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

23. The VCDs made by Zhejiang Huahai Pharmaceutical Co. Ltd. are distributed in the United States by three companies: Major Pharmaceuticals; Teva Pharmaceutical Industries, Ltd.; and Solco Healthcare.[4]

ii. Huahai U.S., Inc.

---

[2] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last accessed June 5, 2019).

[3] Torrent has only recalled VCDs by ZHP.

[4] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm; https://www.nytimes.com/2018/07/16/health/fda-blood-pressure-valsartan.html

24. 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."[5] At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated and/or misbranded generic VCDs in the United States.

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

iii. Harvard Drug Group, LLC

26. Defendant Harvard Drug Group, LLC is a Michigan corporation, with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152.[6]

27. Defendant Major Pharmaceuticals is a Harvard Drug Group company.[7]

28. Defendant Harvard Drug Group is a subsidiary of Cardinal Health.[8]

iv. Cardinal Health, Inc.

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

30. Defendant Cardinal Health, Inc. is the parent corporation of Harvard Drug Company, and through it, Major Pharmaceuticals.

v. Major Pharmaceuticals

---

[5] Huahai US, HOMEPAGE, https://www.huahaius.com/index.html (last accessed Apr. 5, 2019).
[6] https://www.theharvarddruggroup.com/shop/contact/index
[7] https://www.theharvarddruggroup.com/about-us/.
[8] https://www.theharvarddruggroup.com/about-us/
[9] https://www.theharvarddruggroup.com/shop/contact/index

31. Defendant Major Pharmaceuticals, Inc. is a corporation, with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152.

32. Defendant Major Pharmaceuticals, Inc. distributed VCDs supplied by Teva Pharmaceuticals, with API manufactured by Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

vi. Teva Pharmaceuticals USA, Inc.

33. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, with its principal place of business at 1090 Horsham Rd, North Wales, Pennsylvania 19454.[10]

34. Teva Pharmaceuticals USA manufactured VCDs under the Actavis label with API manufactured by Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.[11]

vii. A-S Medication Solutions, LLC

35. Defendant A-S Medication Solutions, LLC is a Nebraska corporation, with its principal place of business at 224 North Park Avenue, Fremont, NE 68025.[12]

36. A-S Medication Solutions is a repackaging company and is listed as the recalling firm for certain batches of VCDs manufactured by Teva Pharmaceuticals and Prinston Pharmaceuticals, Inc., with the active pharmaceutical ingredient ("API") from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.[13]

viii. Prinston Pharmaceutical, Inc.

[10] https://www.tevausa.com/Contact.aspx.
[11] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-issues-voluntary-nationwide-recall-valsartan-and-valsartan.
[12] https://www.nebraska.gov/sos/corp/corpsearch.cgi?acct-number=10119594
[13] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

37. 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., 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 VCDs in the United States.

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

39. Defendant Prinston Pharmaceutical, Inc. manufactured VCDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.[14]

ix. Solco Healthcare US, LLC

40. 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 VCDs in the United States.

x. Teva Pharmaceutical Industries, Ltd.

41. Defendant Teva Pharmaceutical Industries, Ltd. is a finished dose manufacturer who manufactured VCDs.

42. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories

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

and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic VCDs in the United States.

xi. iv. Actavis, LLC

43. Defendant Actavis, LLC is a Delaware corporation, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.[15]

44. Actavis LLC is a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc and [16]

xii. Torrent Private Limited

45. Defendant Torrent Private Limited ("Torrent") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Torrent has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded VCDs in the United States.

xiii. Torrent Pharmaceuticals, Ltd.

46. Defendant Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road,

---

[15] https://icis.corp.delaware.gov/ecorp/entitysearch/NameSearch.aspx; Complaint in Dow Pharmaceutical Sciences Inc. v. Actavis Laboratories UT, Inc. et al. (DNJ 2017): https://insight.rpxcorp.com/litigation_documents/12374243

[16] Complaint in Eli Lilly and Company v. Actavis LLC, et al. - https://insight.rpxcorp.com/litigation_documents/12394629

Suite 102 Basking Ridge, New Jersey 07920. Over seventy percent of Torrent Pharmaceuticals is owned by Torrent. Torrent Pharmaceuticals 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, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded VCDs in the United States.

xiv. Torrent Pharmaceuticals, Inc.

47. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is a wholly-owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of VCDs in the United States.

48. Upon information and belief, Torrent Pharmaceuticals, Inc. is the United States subsidiary of Defendant Torrent Pharmaceuticals, Ltd. and was responsible for distribution of the VCDs at issue to United States consumers.

xv. Bryant Ranch Prepack, Inc.

49. Defendant Bryant Ranch Prepack, Inc. is a California corporation, with its principal place of business at 1919 N. Victory Place Burbank, CA 91504.[17]

50. Defendant Bryant Ranch Prepak, Inc. is a repackager for the Teva and Actavis Defendants, and sold API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.[18]

[17] https://www.brppharma.com/
[18] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

xvi. H J Harkins Co., Inc. dba Pharma Pac

51. Defendant H J Harkins Co., Inc., dba Pharma Pac is a California corporation, with its principal place of business at 1400 West Grand Avenue, Suite F, Grover Beach, CA, 93433.

52. Defendant H.J. Harkins Co. Inc. is a repackager for VCDs manufactured by Prinston Pharmaceutical, Inc., which contained API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

xvii. RemedyRepack, Inc.

53. Defendant RemedyRepack, Inc. is a Pennsylvania corporation, with its principal place of business at 625 Kolter Drive, Suite 4, Indiana, PA 15701.[19]

54. Defendant RemedyRepack is a repackager for VCDs manufactured by Prinston Pharmaceutical, Inc and by Torrent Pharmaceuticals, Ltd., with API coming from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

55. Defendant RemedyRepack is also a repackager for VCDs manufactured by the Hetero and Camber Defendants.

xviii. Northwind Pharmaceuticals

56. Defendant Northwind Pharmaceuticals is an Indiana corporation, with its principal place of business at 9402 Uptown Drive, Suite 1100, Indianapolis, IN, 46256.[20]

---

[19] http://www.remedyrepack.com/RemedySite2/Pages/Home.aspx;

[20] https://bsd.sos.in.gov/PublicBusinessSearch/BusinessInformation?businessId=486568&businessType=Domestic%20Limited%20Liability%20Company&isSeries=False

57. Defendant Northwind Pharmaceuticals is also a repackager for the Teva and Actavis Defendants.[21]

58. On July 27, 2018, the FDA stated in a press release that VCDs manufactured by Northwind Pharmaceuticals were being recalled as part of a recall involving VCDs manufactured by Defendants Teva Pharmaceuticals and Prinston Pharmaceuticals Inc., which contained API manufactured by Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

xix. NuCare Pharmaceuticals, Inc.

59. Defendant NuCare Pharmaceuticals, Inc. is a California corporation, with its principal place of business at 622 West Katella Avenue, Orange, CA 92867.[22]

60. On July 27, 2018, the FDA stated in a press release that VCDs manufactured by NuCare Pharmaceuticals, Inc. were being recalled as part of a recall involving VCDs manufactured by Defendants Teva Pharmaceuticals and Prinston Pharmaceuticals Inc., which contained API manufactured by Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

B. Hetero Labs, Ltd. and Related Defendants

i. Hetero Drugs, Limited

61. Defendant Hetero Labs, Ltd. ("Hetero Labs") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India. Hetero Labs on its own and/or through its subsidiaries regularly conducts business in New Jersey and throughout the United States

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

[22] https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapid=20702699; https://businessfilings.sos.ca.gov/

and its territories and possessions. At all times material to this action, Hetero Labs has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic VCDs throughout the United States.

62. Defendant Hetero Drugs, Limited ("Hetero") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. "Hetero has a strong established global presence with 36 manufacturing facilities and a robust network of business partners and marketing offices strategically located across the world."[23] Hetero on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. Hetero Labs is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic VCDs throughout the United States.

ii. Hetero USA, Inc.

63. Defendant Hetero USA Inc. ("Hetero USA") is "the US representation of HETERO, a privately owned; researched based global pharmaceutical company."[24] Hetero USA is a Delaware corporation with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero USA has been engaged in the

[23] Hetero, GLOBAL FOOTPRINT, https://www.heteroworld.com/global-footprint.php (last accessed June 6, 2019).
[24] Hetero USA, LINKEDIN, https://www.linkedin.com/company/hetero-usa-inc/about/ (last accessed June 5, 2019).

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

iii. Camber Pharmaceuticals, Inc.

64. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a Delaware corporation, with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Camber is the wholly owned subsidiary of Hetero Drugs. At all times material to this action, Camber has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved VCDs throughout the United States.

iv. Preferred Pharmaceuticals, Inc.

65. Defendant Preferred Pharmaceuticals, Inc. is a California corporation, with its principal place of business at 1250 North Lakeview Ave., Unit O, Anaheim CA 92807.[25]

66. Preferred Pharmaceuticals, Inc. is a repackager for VCDs manufactured by the Hetero and Camber Defendants.

v. AvKARE, Inc.

67. Defendant AvKARE, Inc. is a Tennessee corporation, with its principal place of business at 615 N 1st Street, Pulaski, TN 38478-2403.[26]

68. Defendant AvKARE, Inc. serves as a repackager for the Hetero/Camber Defendants, as well as the Teva and Actavis Defendants.[27]

---

[25] https://businesssearch.sos.ca.gov/CBS/Detail; https://www.manta.com/c/mms62wn/preferred-pharmaceuticals-inc

[26] https://tnbear.tn.gov/Ecommerce/FilingDetail.aspx?CN=03707011720024205409516219023805713008322517 2225

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

C. Mylan Laboratories, Ltd. and Related Defendants

i. Mylan Laboratories, Ltd.

69. Defendant Mylan Laboratories, Ltd. ("Mylan Laboratories") is a foreign corporation, with its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Mylan Laboratories 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, Mylan Laboratories has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic VCDs throughout the United States.

70. Defendant Mylan Laboratories, Ltd. is an indirect, wholly owned subsidiary of Mylan N.V.

ii. Mylan Pharmaceuticals, Inc.

71. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a West Virginia corporation, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan Pharmaceuticals is the registered holder of Mylan Laboratories' ANDA for its VCDs. At all times material to this action, Mylan Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic VCDs throughout the United States.

72. Mylan Pharmaceuticals, Inc. is an indirect, wholly owned subsidiary of Mylan N.V.

iii. Mylan, N. V.

73. Defendant Mylan N.V. ("Mylan") is a global generic and specialty pharmaceuticals company registered in the Netherlands, with principal executive offices in Hatfield, Hertfordshire, UK and a Global Center in Canonsburg, Pennsylvania. According to

Mylan's website: "The Chief Executive Officer and other executive officers of Mylan carry out the day-to-day conduct of Mylan's worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania." Mylan Laboratories is a wholly owned subsidiary of Mylan. At all times material to this action. Mylan on its own and/or through its subsidiaries regularly conducted business throughout the United States and its territories and possessions. Mylan has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic VCDs throughout the United States.

iv. Teva Pharmaceuticals USA, Inc.

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

75. According to Teva Pharmaceuticals USA's website, the company is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd."[28]

v. Arrow Pharm Malta, Ltd.

76. Arrow Pharm Malta Ltd. ("Arrow") is a foreign corporation headquartered at HF62 HalFar Industrial Estate, HalFar, BBG 300, Malta. Teva owns the entirety of Arrow, which on its own and/or through its parent company and subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times

[28] https://www.tevagenerics.com/about-teva-generics/who-we-are/

material to this case, Arrow has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded VCDs in the United States.

77. Upon information and belief Arrow Pharm Malta, Ltd. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

vi. Actavis Pharma, Inc.

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

79. Upon information and belief Actavis Pharma, Inc.. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

D. Aurobindo Pharma USA, Inc. and Related Defendants

i. Aurobindo Pharma, Ltd.

80. 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 manufacturing, sale, and distribution of adulterated and/or misbranded VCDs in the United States.

ii. Aurobindo Pharma USA, Inc.

81. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. It is a wholly-owned subsidiary of Aurobindo. At all times material to this case, Aurobindo USA has been engaged in the manufacturing, sale, and distribution of VCDs in the United States.Upon information and belief, Aurobindo USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.[29]

iii. Aurolife Pharma, LLC

82. 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 VCDs in the United States.

iv. Acetris, LLC

83. Defendant Aceteris, LLC is a corporation, with its principal place of business at 3 Pearl Court, Suite 3a, Allendale, NJ 047401.[30]

84. Defendant Acetris, LLC distributes VCDs manufactured by Defendants Aurolife Pharma, LLC.

E. Pharmacy Defendants

v. CVS Health

[29] https://www.aurobindousa.com/wp-content/uploads/Aurobindo_Annual_Report_2016.pdf.

[30] https://www.bloomberg.com/profiles/companies/1511360D:US-acetris-health-llc.

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

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

87. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment:

> provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance exchanges and private health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States.

88. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

89. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

90. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

91. In 2014, CVS Health and wholesaler Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the valsartan-containing drugs purchased by CVS Health were acquired through this joint venture with Cardinal.

92. Defendant CVS Health sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

vi. Walgreens Boots Alliance, Inc.

93. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a national retail pharmacy chain incorporated in the State of Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

94. 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.

95. 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."

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

Defendant Walgreens sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

vii. Express Scripts, Inc.

97. Defendant Express Scripts, Inc. is a corporation, with its principal place of business at One Express Way, St. Louis, MO 63121.[31]

98. Express Scripts, Inc. is a subsidiary of Express Scripts Holding Company.

99. Defendant Express Scripts, Inc. sold VCDs directly to Plaintiffs.

100. Express Scripts, Inc. was acquired by Cigna Corporation in 2018.[32]

viii. Express Scripts Holding Company

101. Defendant Express Scripts Holding Company is a corporation, with its principal place of business at One Express Way, St. Louis, MO 63121.[33]

102. Express Scripts Holding Company is the parent corporation of Defendant Express Scripts, Inc.

103. Express Scripts was acquired by Cigna Corporation in 2018.[34]

ix. Cigna Corporation

---

[31] https://www.walgreensbootsalliance.com/contact/

[32] https://www.sec.gov/Archives/edgar/data/1532063/000119312518074975/d549178dex991.htm.

[33] https://www.express-scripts.com/.

[34] https://www.sec.gov/Archives/edgar/data/1532063/000119312518074975/d549178dex991.htm.

104. Defendant Cigna Corporation is a corporation, with its principal place of business at 900 Cottage Grove Road, Bloomfield, CT 06002.[35]

105. Defendant Cigna Corporation acquired Defendant Express Scripts, Inc. and its holding company, Express Scripts Holding Company in 2018.[36]

x. OptumRx

106. Defendant OptumRx is a Minnesota corporation, with its principal place of business at 2300 Main Street, Irvine, CA 92614.[37]

107. Defendant Optum Rx sold VCDs directly to Plaintiffs.

xi. Optum, Inc.

108. Defendant Optum, Inc. is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[38]

109. Upon information and belief, Defendant Optum Rx is a wholly owned subsidiary of Defendant Optum, Inc.

xii. UnitedHealth Group

110. Defendant UnitedHealth Group is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[39]

111. Upon information and belief, Defendant Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group.

---

[35] https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=172899.

[36] https://www.sec.gov/Archives/edgar/data/1532063/000119312518074975/d549178dex991.htm.

[37] https://www.optumrx.com/public/information-center/public-contact-us

[38] https://www.optum.com/contact.html

[39] https://www.optum.com/contact.html

xiii. Wal-Mart, Inc.

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

113. Defendant Wal-Mart (including Sam's Club) sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

xiv. The Kroger Co.

114. Defendant The Kroger, Co., ("Kroger") is a corporation, with its principal place of business at 1014 Vine Street, Cincinnati, OH 45202.

115. Defendant Kroger sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

xv. Rite Aid Corp.

116. Defendant Rite-Aid Corporation ("Rite-Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania.

117. Defendant Rite-Aid sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

xvi. Albertsons Companies, LLC

118. Defendant Albertsons Companies LLC ("Albertsons") is a limited liability company with its principal place of business in Boise, Idaho.

119. Defendant Albertson sold a large portion of the adulterated and/or misbranded VCDs to U.S. consumers such as Plaintiffs.

xvii. Humana Pharmacy, Inc.

120. Defendant Humana Pharmacy, Inc. is a corporation, with its principal place of business at 500 West Main Street, Louisville, KY 40202.

121. Defendant Humana Pharmacy, Inc. sold VCDs directly to Plaintiffs.

122. Upon information and belief, Defendant Humana Pharmacy, Inc. is a wholly owned subsidiary of Defendant Humana, Inc.

xviii. Humana, Inc.

123. Defendant Humana, Inc. is a corporation, with its principal place of business at 500 West Main Street, Louisville, KY 40202.

124. Upon information and belief, Defendant Humana, Inc. is the parent corporation of Humana Pharmacy, Inc.

F. Wholesaler Defendants

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

126. 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.

127. 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.

128. 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.

129. As mentioned above, Defendant Cardinal Health, Inc. is a corporation, with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.[40]

ii. McKesson Corporation

130. 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.

iii. AmerisourceBergen Corporation

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

G. Doe Defendants

132. 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

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

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.

133. 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

134. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiffs and the Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

135. 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.

136. 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 VALSARTAN-CONTAINING DRUGS

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

138. Valsartan is a generic version of the brand-name medication, Diovan.

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

140. Valsartan 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.

141. Valsartan can be sold by itself or as a single pill which combines valsartan with amlodipine or HCTZ (or both).

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

143. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012.[41]

144. Shortly after the patent for Diovan expired, the FDA began to approve generic versions of the drug.

I. NDMA

145. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[42]

[41] https://www.forbes.com/sites/larryhusten/2012/09/25/another-one-bites-the-dust-diovan-patent-expires-but-generic-valsartan-is-mia/#4b43eaf92833.
[42] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

146. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[43]

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

148. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[44]

149. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[45] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental 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.[46]

150. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[47]

151. Exposure to high levels of NDMA has been linked to liver damage in humans.[48]

152. 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

---

[43] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[44] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[45] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[46] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[47] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[48] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[49]

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

154. 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 that 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.[50]

155. 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."[51]

II. NDEA

156. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[52]

157. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[53]

---

[49] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.
[50] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[51] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[52] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[53] 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.

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

159. 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.

160. Hematological effects were also reported in animal studies.[54]

161. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[55]

162. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[56]

163. 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."[57]

164. 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.[58]

III. OTHER CONTAMINANTS

165. Testing and evaluation is ongoing of VCDs manufactured, distributed, or sold by Defendants. Besides NDMA and NDEA, ongoing investigation suggests other impurities, such as NMBA, may exist as well in the VCDs at issue.

---

[54] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

[55] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

[56] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).

[57] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.

[58] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.

IV. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

166. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[59]

167. 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.[60]

168. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[61]

V. RECALLS

169. Upon information and belief, Plaintiff states that the presence of NDMA and NDEA in the valsartan-containing drugs is due to a manufacturing change that took place on or around 2012.[62]

A. U.S. Recalls

170. 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

---

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

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

[61] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

[62] *See* https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php; *see also* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.

products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[63] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[64]

171. 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."[65]

172. 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.[66]

173. 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."[67]

174. 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."

175. 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."[68]

---

[63] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[64] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[65] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[66] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[67] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[68] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

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

177. 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 unacceptable levels of NDMA.[69] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[70]

178. 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**[71] (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.**

179. 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.[72]

[69] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[70] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[71] https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm.
[72] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

180. 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.[73]

181. 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."[74]

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

B. Recalls in Other Countries

183. 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, losartan and olmesartan."[75]

[73] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[74] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[75] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.

184. 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.[76]

185. 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 is a potential human carcinogen.[77]

C. Defendants Had Actual and/or Constructive Notice of NDMA and/or NDEA Contamination of their VCDs

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

187. NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, or their generic equivalents. Moreover, none of Defendants' VCDs 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.

188. 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,

[76] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines.
[77] http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem.

or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

189. 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.

190. 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."[78]

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

192. 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.

193. 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.

---

[78] *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).

21 C.F.R. § 211.110(c).

194. 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.

195. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' VCDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their VCDs were adulterated and/or misbranded and misbranded as early as 2012.

196. However, there are indications that Defendants had actual knowledge of their VCDs' contamination with NDMA and NDEA, and made efforts to conceal or destroy the evidence.

197. 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.

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

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

200. 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.

201. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated and/or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their generic VCDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their VCDs 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.

202. 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."[79]

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

203. 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.

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.[80]

204. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

205. 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.[81]

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

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

206. 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.[82]

II. MISBRANDED AND ADULTERATED DRUGS

207. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[83]

208. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[84]

209. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[85]

210. 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;"[86]

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;"[87]

---

[82] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[83] 21 U.S.C. § 331(g).
[84] 21 U.S.C. § 331(a).
[85] 21 U.S.C. § 331(c).
[86] 21 U.S.C. § 351(a)(2)(A).
[87] 21 U.S.C. § 351(a)(2)(B).

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. …"[88]

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."[89]

211. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[90]

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."[91]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[92]

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. …"[93]

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."[94]

[88] 21 U.S.C. § 351(b).
[89] 21 U.S.C. § 351(d).
[90] 21 U.S.C. § 352(a)(1).
[91] 21 U.S.C. § 352(c).
[92] 21 U.S.C. § 352(e)(1)(A)(ii)
[93] 21 U.S.C. § 352(f).
[94] 21 U.S.C. § 352(g).

f. "if it is an imitation of another drug;"[95]

g. "if it is offered for sale under the name of another drug."[96]

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."[97]

i. If the drug is advertised incorrectly in any manner;[98] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[99]

212. 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 INGESTED BY PLAINTIFFS WERE NOT VALSARTAN, BUT NEW, UNAPPROVED, VALSARTAN-CONTAINING DRUGS

213. 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.[100]

214. 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,

---

[95] 21 U.S.C. § 352(i)(2).
[96] 21 U.S.C. § 352(i)(3).
[97] 21 U.S.C. § 352(j).
[98] 21 U.S.C. § 352(n).
[99] 21 U.S.C. § 352(p).
[100] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

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."[101]

215. NDMA and NDEA both have the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDMA and NDEA are, by definition, active ingredients in a drug.

216. 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.[102]

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).

217. 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.*

218. 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.

---

[101] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.
[102] *See* 21 C.F.R. § 310.3(h).

219. 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.

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

221. 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.[103] 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.

222. 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.

223. Because the VCDs 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 VALSARTAN-CONTAINING DRUGS

224. 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,"[104] and conform to requirements governing the appearance of the label.[105]

---

[103] *See generally,* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.
[104] 21 C.F.R. § 201.5.
[105] 21 C.F.R. § 801.15.

225. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[106] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

226. "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."[107]

227. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[108]

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

229. It is unlawful to introduce a misbranded drug into interstate commerce.[109] Thus, the valsartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

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

230. 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).

231. 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 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

[106] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[107] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[108] 21 C.F.R. § 201.6; 201.10.
[109] 21 U.S.C. § 331(a).

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.

232. 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.

233. 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.

234. 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.

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

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers,

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

21 C.F.R. § 211.22(a).

236. 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.

217. 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.

218. "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

219. 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).

220. 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.

221. 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.*

222. 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

223. 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.

224. 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.

225. 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).

226. 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).

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

227. 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.

228. 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.

229. 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.

ii. ANDA Applications Must Comply with cGMPs

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

231. 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).

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

232. 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[110] branded drug. Pharmacists, physicians, and patients 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., valsartan or valsartan HCT), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

[110] 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 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."

233. 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.

234. 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.

235. According to the FDA, there are at least sixteen ANDAs approved for generic DIOVAN, nine for generic DIOVAN HCT, nine for generic EXFORGE, and five for generic EXFORGE HCT.

B. Approval of ANDAs Related to Valsartan

i. DIOVAN and EXFORGE Background

236. Valsartan is a potent, orally active nonpeptide tetrazole derivative which causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and post-myocardial infarction. Millions of American consumers use VCDs for the treatment of these serious conditions.

237. Valsartan and its combination therapy with are the generic versions of the DIOVAN and DIOVAN HCT, which were marketed in tablet form by Novartis AG ("Novartis") beginning in July 2001 (in tablet form) and March 1998, respectively, upon approval by the FDA.

238. Valsartan's combination therapy with amlodipine, as well as the combination therapy of valsartan, amlodipine and hydrochlorothiazide, are the generic versions of Novartis's

branded products EXFORGE and EXFORGE HCT. Novartis received the FDA's approval for EXFORGE in June 2007 and for EXFORGE HCT in April 2009.

239. These Valsartan based branded drugs proved to be blockbuster products for Novartis. Globally, DIOVAN and DIOVAN HCT generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States. The same year, EXFORGE and EXFORGE HCT had $325,000,000 in U.S. sales and $884,000,000 globally.

240. DIOVAN's, DIOVAN HCT's, EXFORGE's, and EXFORGE HCT's FDA-approved labels specify the active and inactive ingredients. None of the contaminants at issue here (including NDMA, NDEA, or other nitrosamines) are FDA-approved ingredients of DIOVAN, DIOVAN HCT, EXFORGE, or EXFORGE HCT. Nor are any of these contaminants FDA-approved ingredients of any generic valsartan-containing product approved pursuant to an ANDA.

241. Novartis's DIOVAN and EXFORGE patents expired in September 2012. Defendant Mylan launched a DIOVAN HCT generic in or about September 2012 when its valsartan HCT ANDA was approved by the FDA. Generic versions of the other drugs followed in the intervening years.

ii. ANDA Applications for Generic Valsartan

242. Almost a full decade before the DIOVAN patents were set to expire, generic drug manufacturers started filing ANDA applications for their own generic versions of the Valsartan drug.

243. Hatch-Waxman rewards the first generic company to file a substantially complete ANDA containing a Paragraph IV certification with a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is triggered upon either a first

commercial marketing of the drug (including of the RLD) by the 180-day exclusivity holder or the date on which a court has entered a judgment finding that the patent subject to the Paragraph IV certification is invalid, unenforceable, or not infringed.

244. On December 24, 2004, Ranbaxy Labs ("Ranbaxy") filed the first ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

245. On January 7, 2005, Teva filed the second ANDA application for Valsartan (the generic equivalent of the DIOVAN product), for which it received tentative approval on January 7, 2005.

246. On September 15, 2008, Mylan filed an ANDA application for Valsartan (the generic equivalent of the DIOVAN product).

247. Upon information and belief, in the intervening years after these three initial ANDA applications, all other Defendants filed ANDA applications for either Valsartan (the generic equivalent of the DIOVAN product), Valsartan hydrochlorothiazide (the generic equivalent of the DIOVAN HCT product), Valsartan Amlodipine (the generic equivalent of the EXFORGE product), and Valsartan Amlodipine Hydrochlorothiazide (the generic equivalent of the EXFORGE HCT product).

iii. Entry of Generic DIOVAN Was Delayed Due to Gross cGMP Violations by First ANDA Filer Ranbaxy

248. Despite the number of ANDAs that had been filed as early as 2004, when DIOVAN's patent expired in 2012, no generic entered the market.

249. As the first to have filed their ANDA application in December of 2004, Ranbaxy was entitled to exclusivity, and as such, no other ANDAs would be approved until Ranbaxy received final approval.

250. Defendants Mylan and Teva were among those who had tentative approval and were ready to launch their generic DIOVAN Product upon expiration of the DIOVAN patent in 2012.

251. Indeed, Defendant Mylan launched its generic DIOVAN HCT product, for which it had filed an ANDA and received approval, on September 21, 2012, the same day the DIOVAN patent was set to expire.

252. However, Ranbaxy Pharmaceuticals (the generic company entitled to exclusivity because they were the first to file their ANDA application) was unable to achieve final approval from the FDA for its generic DIOVAN, thus effectively preventing other generic competition under the Hatch-Waxman Act until Ranbaxy achieved FDA approval and began to market its generic product. This delay in approval was due to gross manufacturing defects plaguing Ranbaxy's Indian API manufacturing facilities.

253. Indeed, in the intervening years between initially filing its ANDA application and the expiration of the DIOVAN patent, Ranbaxy was under siege with civil and criminal investigations by the United States due to grossly negligent and criminal acts relating to its pharmaceutical drug manufacturing processes in India. Among these acts were failures to meet minimum safety standards at manufacturing sites and making material false statements to the FDA.

254. These issues delayed approval of Ranbaxy's generic DIOVAN approval and subsequent entry into the market.

255. As the ANDA filers in line after Ranbaxy, Mylan and Teva were especially cognizant of the delay in approval, as, by law, their applications would not receive approval until Ranbaxy achieved final approval. But more importantly, Mylan and Teva were aware of

the role the gross manufacturing practices of Ranbaxy in their Indian operations, and the subsequent civil and criminal investigations into those practices, was playing in the delay.

256. While Mylan did have final approval to launch DIOVAN HCT (and did ultimately launch their generic DIOVAN HCT product upon patent expiration in September of 20120), they still had no approval to launch a pure DIOVAN generic. Consequently, in 2012, Mylan Labs sued the FDA requesting declaratory and injunctive relief arising out of the FDA's "arbitrary, capricious, and unlawful decision" to grant exclusivity to Ranbaxy, and for refusing to grant final approval of Mylan's ANDA application for valsartan.

257. As to Mylan's pure DIOVAN patent suit, ultimately the Court sided with Ranbaxy and the FDA, and found in their favor on December 27, 2012, dismissing Mylan's case.

258. A year and a half later, when still no generic valsartan had entered the market despite the patent's expiration in 2012, a law firm claiming to represent an unnamed "generic manufacturer" filed a citizen's petition with the FDA in May of 2014, arguing for the same exact relief that Mylan had requested in their original suit against the FDA.

259. The citizen's petition (on behalf of the unnamed "generic manufacturer with ANDA approval") detailed the widespread fraudulent testing, widespread cGMP problems, lack of information in batch records, incomplete failure investigations, warning letters, and criminal pleas that plagued Ranbaxy's Indian manufacturing plants.

260. The relief the citizen petition sought was the precise relief that Mylan was seeking in their previously dismissed suit – for Ranbaxy's valsartan ANDA approval to be withdrawn, and for all other pending ANDAs for valsartan to receive final approval and be permitted to launch their products into the market .

261. On May 14, 2014, Teva Pharmaceuticals filed a response to the initial Citizen Petition, agreeing that the "well-documented and serious data-integrity violations" at the Ranbaxy

facilities should prevent it from receiving final approval for its valsartan generic, and asking that Teva be treated as the first filer and be entitled to exclusivity for 180 days.

262. Appended as an exhibit to Teva's supplement regarding the valsartan generic was a letter from Teva's General Counsel at the time, Ildiko Mehes. The letter detailed the "unprecedented set of circumstances" and the "impact on the consumers." The letter also detailed Ranbaxy's "persistent problem with data integrity" and "inadequate control measures for insuring the integrity of data."

263. However, these self-serving (and, as it will turn out, hypocritical) submissions on behalf of the "unnamed generic manufacturer," Mylan, and Teva were for naught, as the FDA eventually gave Ranbaxy final approval on its valsartan in June of 2014.

264. Six months later, after Ranbaxy's period of exclusivity expired, Mylan's generic DIOVAN product launched on January 5, 2015, and Teva's generic VCDs launched January 6, 2015. The entry rest of the generic equivalents of these drugs followed thereafter.

265. Par Pharmaceuticals received approval of the first generic EXFORGE in September 2014, and Teva received approval of the first generic EXFORGE HCT in December 2014. The entry rest of the generic equivalents of these drugs followed thereafter.

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

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

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

i. ZHP's Inadequate Manufacturing Processes

268. 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.

269. ZHP serves as a contract API manufacturer of numerous defendants' VCDs as set forth above, 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.

270. 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.

271. 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.

272. 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."

273. 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.

274. 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]."[111]

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

275. 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 and NDEA.

276. 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.

277. 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]."

278. 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)."

279. 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.

280. ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." More specifically, ZHP "approved a [V]alsartan API process change . . . that included the use of the solvent [redacted]. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities[, such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process."

281. The FDA added that ZHP "also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in [its] [V]alsartan API before [it] approved the process change. [ZHP is] responsible for developing and using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes."

282. 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.

283. 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)."

284. After the recalls of ZHP's VCDs, 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[112] of 96 ng/day or 0.3 ppm.[113] Specifically, VCDs 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.[114] ZHP

[112] To be clear, ZHP's valsartan products should not contain any NDMA.

[113] 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).

[114] *Id.*

valsartan API manufactured for Teva and Torrent Pharmaceuticals contained similarly high levels of NDMA.

285. 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[115] of 26.5 ng/day or 0.083 ppm. Specifically, FDA testing reveals up to 1,310 ng of NDEA in Torrent Pharmaceuticals' VCDs. ZHP valsartan API manufactured for Teva contained similarly high levels of NDEA (up to 770 ng).

ii. Aurobindo's Inadequate Manufacturing Processes

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

287. Aurobindo manufactures VCD for each Aurobindo Defendant at these facilities, and Aurobindo Defendants thus have quality assurance obligations with respect to Aurobindo's processes and finished products as set forth above pursuant to federal law.

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

289. 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."

[115] To be clear, Torrent Pharmaceuticals' and Teva's valsartan products should not contain any NDEA.

290. 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."

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

292. 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."

293. 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."

294. 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."

295. 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.

296. 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."

297. Additionally, while Aurobindo claimed to have performed tests and quality control activities on API as a result of the FDA's investigation into adulterated VCDs, 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.

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

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

299. 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.

300. After the recalls of Aurobindo's VCDs, 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[116] of 26.5 ng/day or 0.083 ppm.[117]

iii. Mylan's Inadequate Manufacturing Processes

301. While ZHP and Aurobindo began as foreign companies who eventually expanded their operations to the United States, Mylan's history begins in the United States back in 1961, in White Sulfur Springs, West Virginia.

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

[117] 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).

302. From the founding of the company, to roughly the mid-2000s, Mylan either manufactured their own products domestically in the United States, or contracted with foreign companies to order API for their finished dosage products.

303. However, in late 2005, Mylan's CEO at the time, Robert Coury, was facing a crisis due to the fact that the US-based company was losing market share to Indian drug companies that made their own API in-house and operated at rock-bottom costs. At the time, Mylan was having to order API from Chinese and Indian suppliers.

304. Consequently, in December of 2005, Coury hammered out a deal to acquire Matrix Laboratories, an India-based company which had been one of Mylan's ingredient suppliers. At the time of the acquisition of Matrix Laboratories, a former Ranbaxy employee named Rajiv Malik was the CEO of Matrix.

305. After the Mylan acquisition in 2006, Malik became the executive vice president in charge of global technical operations.

306. Malik's impact on Mylan was immediate – he reoriented the company towards India. Very quickly, the number of drug applications for generics Mylan submitted to the FDA tripled, and the approvals doubled.

307. Indeed, Malik's compensation structure was based, in part, on the number of ANDA applications filed with global regulators.

308. As the focus shifted to bringing more and more drugs to market, employees in both India and the United States began to experience a shift in the company, where speed was prized above all else. Employees who insisted on adhering to cGMPs felt sidelined and were tagged as slow.

309. In 2013, Malik was tasked with overseeing Mylan's biggest foreign acquisition yet – a $1.6 billion purchase of Agila Specialities, a manufacturing facility in India.

310. In comments regarding the potential acquisition, Mylan CEO Heather Bresch (daughter of US Senator Joe Manchin) touted the "state-of-the-art, high quality" manufacturing platforms in the industry.

311. However, months after Mylan announced the acquisition, the FDA conducted an investigation of the facility in June of 2013. In a scathing investigation report, it found that key pieces of equipment were stored in non-sterile areas, and then never resanitized before use; employees failed to wash their hands in the bathroom; technicians were wearing gloves that were flaking and had pinholes; and supposedly sterile gloves were found to be stored in boxes with crushed insects.

312. Making matters worse, after the June inspection, in a letter written by the FDA in September, the FDA found that Agila's written response "minimizes the importance of ensuring glove integrity and its potential impact on product quality." It also found that the issues led the FDA to "question [Agila's] understanding of basic microbiology and microbial controls that are critical for the manufacture of sterile products."

313. However, despite these gross manufacturing issues, Mylan moved full-speed ahead on its billion-dollar acquisition, eventually obtaining the company and their manufacturing facilities.

314. Throughout 2014 and 2015, the FDA continued to investigate Mylan's Indian manufacturing facilities, routinely uncovering a multitude of violations of the cGMPs, and finding that Mylan responded with letters that lacked corrective action. These violations included failure to establish and follow written procedures to prevent microbiological contamination of drug products, lack of assurance that the manufacturing facilities were sterile, and failures to thoroughly investigate unexplained discrepancies in batches or whether the components met specifications.

315. In 2015, a former Mylan employee sat down with FDA employees and alleged that the research and development centers in Hyderabad had become a hub for data fraud.[118]

316. The Mylan whistleblower identified specific applications for drugs that were due to be launched into the American market, claiming that in order to generate passing results for some drug products, Mylan had manipulated the testing, by switching the tests from batch testing to pilot batches (which were easier to control, but not as reliable in ensuring the results as they were smaller in size).[119]

317. The Mylan whistleblower also claimed that the Mylan team had evolved its fraudulent methods to evade detection. For example, instead of deleting manipulated data from the plant's software systems, which would have left a trail of metadata that could be uncovered by the FDA, plant managers were deliberately corrupting the data they wanted to hide. [120]

318. In July of 2016, upset by the failure of the FDA to investigate, the Mylan whistleblower sent an email to FDA officials that said: "I learned that Mylan's strategy of providing employment to FDA members has been working very well…Perhaps the agency awaits a definitive tragedy to occur on U.S. soil to due sub-standard generic products not meeting the safety & efficacy standards." [121]

319. The email had the intended effect. Two months later, in September 2016, the FDA inspected the Mylan India facilities.[122]

320. Over the course of the week-long inspection, the FDA found evidence that the plant's software system was riddled with error messages showing "instrument malfunction," or

[118] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 328.
[119] *Id.*
[120] *Id.*
[121] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 329.
[122] *Id.*

"power loss," as though Mylan was literally pulling the plug from the wall to stop the creation of metadata showing failed testing.

321. In confidential correspondence with the FDA, Mylan tried to explain the high number of data error messages (42 over a seven-day period), but could only try to explain by saying there was accidental knocking of cables off of tables, or through electronic loss of signals. For another error that was observed (150 times over seven days), the partial explanation given by Mylan was that some software settings led to the "unintended consequence of a number of repetitive error messages." [123]

322. The FDA didn't buy these excuses. In a stern warning letter sent to Malik in April of 2017, the FDA effectively froze the site's applications until the company took corrective actions. The letter noted that Mylan's quality systems did not "adequately ensure the accuracy and integrity of the data." [124]

323. But Mylan's issues were not solely limited to its India operations. Several months after the April 2017 letter regarding the India operations, Mylan operations in West Virginia were under scrutiny. The allegations were that laboratory technicians had failed to investigate anomalous results and had instead falsified records to cover-up any anomalous results. Regulators were "stunned" by the lapses, finding the practices "egregious," and questioned whether Mylan was being "transparent at all of its sites." [125]

324. The inspectors also found bins full of shredded documents, including quality-control records, in parts of the factory where every piece of paper is supposed to be saved. [126]

---

[123] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 331
[124] *Id.*
[125] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 332
[126] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost

325. The list of alleged infractions became so long that a fourth inspector was added. A warning letter, the FDA's strongest rebuke, was drafted. [127]

326. Ultimately, the FDA's director of the Office of Manufacturing Quality, Tom Cosgrove, made the controversial decision, over the strenuous objections of staff in two separate FDA divisions, to downgrade the investigators' negative findings at Morgantown, from Official Action Indicated to Voluntary Action Indicated. [128]

327. In an email to FDA colleagues, Cosgrove acknowledged their view that the company's practices were "more widespread and that Mylan's investigation was insufficient," but ultimately defended his decision and said that he had no reason to believe that Mylan would not "remediate voluntarily."

328. However, while Mylan's Morgantown plant was no longer receiving intensive agency scrutiny, it did little to resolve the issues.

329. In early 2018, a whistleblower from inside the Morgantown plant reached out to the FDA to report deteriorating conditions, from understaffing to cleaning lapses. The whistleblower from inside the plant claimed that Mylan management was focused on creating a "façade of documents" to fend off the FDA, according to an agency memo that detailed the allegations. The whistleblower also notified the FDA that Mylan had brought in a team of employees from India to the Morgantown, WV facility, to rapidly close a backlog of company investigations, and that employees were instructed not to question their work.[129]

---

[127] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost

[128] *See* Katherine Eban, *Bottle of Lies* (2019) at p. 333

[129] *Id.*

330. Consequently, the FDA inspected the Morgantown, WV facility again in March and April of 2018. The inspectors found a host of new violations, including that Mylan's manufacturing equipment was not cleaned at appropriate intervals to prevent contamination, and that Mylan's attempts to address the purported testing from the 2016 inspection was "not adequate." [130]

331. On November 20, 2018, Mylan initiated a recall on the consumer level of select lots of VCDs, due to adulteration of the products with NDEA.

iv. Hetero's Inadequate Manufacturing Processes

332. Defendant Hetero maintains six API manufacturing facilities in India, which have been approved by the FDA to produce active ingredients for drugs being sold and marketed in the United States.

333. Hetero has a history of deviations from FDA's cGMP standards.

334. In December of 2016, during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that Hetero Quality Assurance technicians and "other individuals" were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection. According to a scathing letter, the FDA noted that the following occurred:

a. Hetero employees brought in a document shredder into the "DOCUMENTS STORAGE AREA" four days prior to the FDA inspection;

[130] https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost

b. The FDA observed extensive shredding of what appeared to be "controlled documents" as well as "extensive signing of documents" by Quality Assurance technicians. The FDA noted that the documents were of a color consistent with batch packaging records and batch manufacturing record. Hetero failed to maintain documentation of what had been shredded;

c. One day prior to the FDA inspection a Hetero contract employee in the Quality Assurance division removed documents from the shredder and placed them in his pocket; and

d. At 1:13 am the morning the FDA inspectors were set to arrive at Hetero for their regulatory inspections, individuals were seen shredding documents.

335. In addition to the documented destruction of these manufacturing records, the FDA further observed that production and control records were not prepared for each batch of drug product produced and did not include complete information relating to the production and control of each batch.

336. Additionally, data derived from Hetero's programmable logic controller for compression machines was inconsistent with batch records and validation reports that were submitted to the FDA in support of applications to manufacture and market drugs in the United States.

337. Hetero also failed to include findings of any investigations and follow-up that occurred as a result of investigations into complaints about their drugs.

338. During the December 2016 inspection, equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero drug products.

339. During the December 2016 visit, FDA inspectors found that "accuracy, sensitivity and reproducibility of test methods" were not established and documented.

340. In an August 15, 2017, warning letter, the FDA strongly recommended that Hetero engage "a consultant, qualified as set forth in 21 CFR 211.34" to assist Hetero Labs in meeting cGMP requirements, but that, ultimately, "executive management remains responsible for fully resolving all deficiencies and ensuring ongoing cGMP compliance."

341. In February of 2018, FDA investigators discovered other manufacturing flaws at an API Manufacturing facility.

342. For example, the FDA found that there was a "failure" by Hetero to "thoroughly review any unexplained discrepancy and failure of a batch or any of its components to meet any of its specifications," whether or not the batch had been already distributed.

343. The FDA investigators further found during that February 2018 inspection that Hetero employees who were engaged in the processing, holding and testing of a drug product lacked the training and experience required to perform their assigned functions. Indeed, in a walk-through with FDA investigators, several quality-control personnel could not explain their assigned functions and processes after "repeated opportunities" to do so.

344. Additionally, FDA investigators concluded that there was "no assurance" that equipment used in API production was being maintained and/or kept under proper conditions for manufacturing operations "to prevent the contamination of the products handled and/or processed in the equipment." Likewise, equipment at the Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero's drug products.

345. After the recalls of Hetero's VCDs, FDA Laboratory Analysis testing would later reveal that valsartan 320mg API manufactured by Hetero contained NDMA levels in excess of the FDA's interim limits[131] of 96 ng/day or 0.3 ppm.[132]

VIII. WARRANTIES COMMON TO ALL MANUFACTURER DEFENDANTS

346. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[133] 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 VCDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic VCDs was bioequivalent to their RLDs.

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

348. Each Defendant's VCDs is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved VCD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers like Plaintiffs of the "sameness" of their products to the VCD's RLD, and that their products were consistent

---

[131] To be clear, Hetero's valsartan products should not contain any NDMA.

[132] 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.

[133] 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).

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.

349. By introducing their respective VCDs 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 VCDs are in fact the same as and are therapeutically interchangeable with their RLDs.

350. 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 VCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

351. The presence of nitrosamines in Defendants' VCDs: (1) renders Defendants' VCDs 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' VCDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' VCDs 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 VCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

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

353. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA, NDEA, and other nitrosamines are not FDA-approved ingredients in VCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendants' VCDs means that Defendants violated implied warranties to Plaintiffs and their physicians. The presence of NDMA or NDEA in Defendants' VCDs results in Defendants' VCDs 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.

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

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

A. ZHP Defendants' Warranties

356. On its January 29, 2019 website,[134] 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

[134] ZHP completely changed its website sometime in February or March 2019.

designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."

357. Huahai US assisted Prinston in obtaining approval of its ANDA for its VCDs.

358. Prinston lists its VCDs as equivalent to Diovan on its website.[135]

359. 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."[136]

360. 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."[137]

361. Solco lists its VCDs on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's valsartan Prescribing Information.[138]

B. Hetero Defendants' Warranties

362. In touting itself, Hetero claims that it has "over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico and Indonesia. Approved by stringent global regulatory authorities, Hetero facilities have integrated quality systems and processes to ensure adherence to cGMP (current Good Manufacturing practices). They are also vertically integrated and can be utilised for large-

---

[135] Prinston, PRODUCT LIST, http://www.prinstonpharm.com/Products_List.html#v (last visited Apr. 5, 2019).
[136] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last accessed Apr. 5, 2019).
[137] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Apr. 5, 2019).
[138] Solco, VALSARTAN TABLETS, http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last accessed Apr. 5, 2019).

scale production of APIs, formulations in various dosage forms rapidly. We make continuous investments in upgradation of manufacturing facilities with special emphasis on deploying advanced machinery and adopting latest technologies to comply with 21 CFR. Besides enabling us consistently produce high quality medicines at an affordable cost, it also helps us in passing through regulatory audits with relative ease. It is these advantages that make us the partner of choice for major global pharmaceutical companies."[139]

363. Indeed, Hetero further describes itself as "a research-driven pharmaceutical company, is committed to the development, manufacturing and marketing of active pharmaceutical ingredients (APIs), intermediates and finished dosages. Today, Hetero is recognized as a world leader in process chemistry, API manufacturing, formulation development, manufacturing and commercialization. Hetero has around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various Ministries of Health and regulatory authorities like US FDA, WHO, MCC - South Africa, MHRA-UK, TGA – Australia, PMDA – Japan, KFDA (Korea) among others. The company has a rich manufacturing product portfolio of over 200 products across a wide range of therapeutic categories. Hetero has a strong global presence in over 120 countries and has been offering API's and generic formulations to partners across the globe. . . . . Hetero, a privately-owned company, is recognized as one of the top 10 companies in the Indian pharmaceutical industry with an annual turnover of US$ 1.2 billion. With a

[139] Hetero, MANUFACTURING CAPABILITIES, https://www.heteroworld.com/manufacturing.php (last accessed June 6, 2019).

dedication and support of its 15,000 employees, Hetero continues its commitment to manufacture high-quality drugs and save millions of lives across the world."[140]

364. Specifically with respect to its manufacturing of API, Hetero purports to be "proficient in achieving regulatory approvals worldwide of both APIs and formulations. With an integrated quality system to ensure adherence to cGMP practices, Hetero is committed to quality and its manufacturing facilities are approved by global regulatory agencies. In addition, Hetero continues to invest in its state-of-the-art manufacturing facilities and capabilities to ensure that it is able to provide the highest level of quality standards in the pharmaceutical industry."[141]

365. Hetero likewise goes to great lengths in describing its products as the same as the brand drug. It states that its generic drugs are "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs. . . . . Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other

[140] Camber, OUR PARENT COMPANY: HETERO, http://camberpharma.com/about-us/hetero (last accessed June 6, 2019).
[141] Camber, GLOBAL RESOURCES, http://camberpharma.com/global-resources (last accessed June 6, 2019).

drugs already on the market. . . . . To find out if there is a generic equivalent for your brand-name drug, visit FDA.gov to view a catalog of FDA-approved drug products, as well as drug labeling. Since there is a lag time after generic products are approved and they appear in the "Orange Book", you should also consult the most recent monthly approvals for "First Generics" at FDA.gov."[142]

366. Camber compares its valsartan to DIOVAN on its website's product catalog.[143]

C. Mylan Defendants' Warranties

367. Mylan has a section of its website discussing generics, and claims that "[g]eneric pharmaceuticals are the same as existing approved brand-name drugs in active ingredient, dosage form, safety, strength, route of administration, quality and performance characteristics. Generic medications are just as safe and effective as their brand-name counterparts, and often cost less." [144]

368. Mylan also guarantees that "consumers can be assured that FDA-approved generic products have net the same rigid manufacturing standards as the innovator drug."

369. According its website as of November 2018, "Mylan offers one of the broadest portfolios of active pharmaceutical ingredients (API)—the ingredients responsible for the therapeutic effects of different medicines—to more than 100 countries. Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines. Direct access to API makes Mylan one of the few global generics companies with a comprehensive, vertically integrated

[142] Camber, ABOUT GENERICS, http://camberpharma.com/generics (last accessed June 6, 2019)
[143] Camber, PRODUCT, http://camberpharma.com/products?&filter=V (last accessed June 6, 2019).
[144] https://www.mylan.com/en/products/generics (last accessed June 5, 2019).

supply chain and helps us maintain deep insight into diverse markets and therapeutic segments. . . . . With a commitment to quality, state-of-the-art API manufacturing facilities, global regulatory accreditations, a strong pipeline and speed-to-market capabilities, Mylan is an ideal API partner."[145]

370. Mylan's online product catalog lists its generic VCDs as equivalent to their RLDs.[146]

D. Torrent Defendants' Warranties

371. Torrent Pharmaceutical's website states that they, "strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."[147]

E. Aurobindo Defendants' Warranties

372. Aurobindo's website states that it is "Committed to Quality and Safety."[148]

373. On January 6, 2015, Aurobindo announced that it had received FDA approval to manufacture and market valsartan, adding that valsartan is the "the generic equivalent to the reference listed drug product (RLD) Diovan®."

[145] Mylan changed this part of its website sometime after November 2018.
[146] Mylan, PRODUCT CATALOG, https://www.mylan.com/en/products/product-catalog/ (last accessed June 6, 2019) (clicking on the relevant product shows the page and RLD reference for each VCD).
[147] Torrent Pharmaceuticals, MANUFACTURING, http://www.torrentpharma.com/Index.php/site/info/manufacturing (last accessed June 5, 2019).
[148] Aurobindo, HOMEPAGE, https://www.aurobindo.com/ (last visited June 5, 2019).

374. According to Aurobindo USA, "[a]s a truly integrated company, we assure continuity and quality from start to finish."[149] Aurobindo also "[s]eek[s] to attain the highest quality standards."[150]

375. Aurobindo USA's website lists DIOVAN as its valsartan's "Brand Reference."[151]

376. 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."[152]

F. Teva Defendants' Warranties

377. Teva has a "Generics FAQs" on its website.[153] In response to the question "Are generic drugs safe?" Teva states the following:

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

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

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

---

[149] Aurobindo USA, AUROCONTROL, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last accessed June 5, 2019).
[150] Aurobindo USA, OUR STORY, https://www.aurobindousa.com/company/our-story/ (last accessed June 5, 2019).
[151] Aurobindo USA, VALSARTAN TABLETS, https://www.aurobindousa.com/product-category/valsartan-tablets/ (last accessed June 5, 2019).
[152] Aurolife, ABOUT AUROLIFE, http://aurolifepharma.com/aboutus.html (last accessed June 5, 2019).
[153] Teva, PRODUCTS, *at* http://www.tevapharm.com/our_products/generic_qa/ (last accessed June 5, 2019).

379. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

380. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."[154]

381. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[155]

382. In a May 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their VCDs were "bioequivalent" to their RLDs.

383. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our

---

[154] Teva, Company PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/ (last accessed June 5, 2019).
[155] *Id.*

manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[156]

384. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."[157]

385. Teva USA maintains a Brand-to-Generic Medication Reference on its website.[158] Before its recall of VCDs, this Reference included VCDs and their RLD equivalents.

IX. WARRANTIES COMMON TO ALL RETAIL PHARMACY DEFENDANTS

386. 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.

387. 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.

---

[156] Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/ (last accessed June 5, 2019).
[157] Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/ (last accessed June 5, 2019).
[158] Teva USA. PATIENTS: RESOURCES, https://www.tevagenerics.com/patients/resources/ (last accessed June 5, 2019).

X. WHOLESALE DISTRIBUTOR DEFENDANTS' WARRANTIES

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

XI. REPACKAGER AND RELABELER DEFENDANTS' WARRANTIES

389. By selling drugs in the stream of commerce, 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.

390. 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

391. The recall of Defendants' VCDs is only the tip of the iceberg. Just two weeks after the FDA's initial recall announcement, the FDA issued another announcement expanding the recall to other VCDs manufactured at another plant in India, and by other non-parties. *See supra* n.4. On August 20, 2018 the FDA announced that it was going to test all VCDs for NDMA.[159] Because of Defendants' and non-parties' ongoing fraud and deception, the full scope of Defendants' and non-parties' unlawful conduct is not yet known. Indeed, grossly inadequate manufacturing processes have been observed in Aurobindo's facility

[159] FDA Statement, STATEMENT FROM FDA COMMISSIONER, *at* http://freepdfhosting.com/1c7e5ed26e.pdf (last accessed June 5, 2019).

as recently May, 2019 (*one month prior to the filing of this Complaint)*, nearly a year after the recall of the VCDs.

PLAINTIFFS' INJURIES

392. Plaintiffs were prescribed generic valsartan during the time in which Defendants' VCDs were contaminated with NDMA, NDEA, or other nitrosamines.

393. The VCDs ingested by Plaintiffs were designed, manufactured, marketed, sold, and/or distributed by the above-captioned defendants, though the drugs turned out not to be generic valsartan, but instead unapproved, unregulated, VCDs containing dangerous levels of nitrosamines.

394. As a result of Plaintiffs' ingestion of the VCDs, Plaintiffs developed and were diagnosed with cancer, which caused permanent and disabling injuries and/or death.

I. CAUSATION

395. Plaintiffs would not have consented to taking the VCDs at issue, had Plaintiffs 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, and/or other nitrosamines.

396. Plaintiffs and Plaintiffs' physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of the VCDs.

397. Plaintiffs 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.

398. Plaintiffs and Plaintiffs' physicians chose to take and prescribe the VCDs 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. MANY PLAINTIFFS CONTINUED TO RECEIVE VCDS CONTAINING NITROSAMINES EVEN AFTER THE RECALLS BEGAN

237. During the course of the recalls of VCDs, FDA set interim limits for the amounts of certain nitrosamines, including NDEA and NDMA, which could be present in VCDs before a recall would be necessary.

238. Notably, these interim limits were, by definition, higher than what FDA normally would have permitted.

239. Patients receiving recall notices and seeing information on the news were also advised not to stop taking their VCDs until they had been able to speak with their physicians and obtain new prescriptions.

240. In many instances, patients, such as Plaintiffs, spoke with their physicians and were switched to another brand of VCDs which were later also subsequently determined to contain high levels of nitrosamines and recalled.

241. Meanwhile, many Plaintiffs had already been diagnosed with cancer prior to the announcement of the recall but continued to take the nitrosamine-laden VCDs until recalls were announced.

242. For each of these Plaintiffs who continued to ingest VCDs containing dangerous levels of nitrosamines such as NDMA and NDEA after being diagnosed with cancer, their conditioned were prolonged and worsened with each day that they continued to unknowingly expose themselves to more and more of these dangerous substances.

III. PLAINTIFFS' RESULTING DAMAGES AND INJURIES

399. Plaintiffs suffered serious personal injuries 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.

400. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiffs suffered and will continue to suffer from severe injuries and damages, including but not limited to severe personal injuries, great emotional distress, and mental anguish.

401. As a result of use of contaminated valsartan as designed, manufactured, promoted, sold and/or supplied by Defendants, and as a result of the negligence, callousness and the other wrongdoing and misconduct of the Defendants as described herein:

a. Plaintiffs were injured and suffered injuries to Plaintiffs' body and mind, the exact nature of which are not completely known to date;

b. Plaintiffs sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiffs incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages Plaintiffs suffered;

d. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

IV. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

402. Plaintiffs had no reason until recently to suspect that their 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 VCDs caused Plaintiffs' injuries (or that Plaintiffs' VCDs were contaminated at all). For these reasons, Plaintiffs' Complaints were filed within the time period allowed by the applicable statutes of limitations.

403. 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.

404. 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.

405. 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 VCDs, 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.

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

407. 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 VCDs, particularly when the drugs ceased to be the same as its brand-name counterpart.

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

409. 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.

410. 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

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

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

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

415. Defendants knew, and/or had reason to know, that the VCDs ingested by Plaintiffs were defective, unreasonably dangerous and not safe for human consumption, as they

contained dangerously high levels of carcinogenic compounds, namely NDMA and NDEA, and other nitrosamines.

I. REPRESENTATIONS

416. Defendants designed, manufactured, labeled, marketed, packaged, distributed, and promoted the VCDs ingested by Plaintiffs for treatment of high blood pressure and other indications.

417. Defendants misrepresented, downplayed, and/or omitted the safety risks of the VCDs 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.

418. 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 VCDs ingested by Plaintiffs, which contained carcinogenic compounds.

419. Defendants knew and/or should have known that their representations and suggestions to physicians that their valsartan-containing drugs 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.

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

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

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

423. 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.

424. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the use of the VCDs 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.

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

426. 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.

427. Had Defendants performed adequate tests on the valsartan-containing drugs, these defendants would have discovered that these drugs were not safe for human consumption.

CLAIMS FOR RELIEF

I. STRICT LIABILITY- MANUFACTURING DEFECT

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

429. At all times herein mentioned, Defendants designed, distributed, manufactured, sold, tested, and marketed the drugs ingested by Plaintiffs to patients and physicians.

430. At all relevant times, the medication ingested by Plaintiffs were expected to and did reach Plaintiffs without a substantial change in its condition as manufactured, distributed, and sold by Defendants.

431. At all relevant times, the medications ingested by Plaintiffs contained manufacturing defects, in that they differed from the approved design and specifications of the generic drug, valsartan.

432. At all relevant times, the medications ingested by Plaintiffs further contained manufacturing defects, in that they were not bioequivalents to Diovan, thereby rendering these products unreasonably dangerous to patients such as Plaintiffs.

433. Defendants were required to manufacture a drug that conformed to FDA-approved specifications, such that the drugs manufactured were equal substitutes to their brand-name equivalent, Diovan, which did not contain nitrosamines. These drugs were required to be biologically the "same as an already marketed brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[160]

434. Defendants failed to meet the requirements mentioned in the paragraph above by utilizing a flawed and unlawful manufacturing process that was unvalidated and unsafe and by violating Current Good Manufacturing Practices.

---

160 https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

435. Instead, Defendants manufactured a different drug, containing additional active and harmful ingredients.

436. At all relevant times, the medications ingested by Plaintiffs were used in a manner that was foreseeable and intended by Defendants.

437. As a direct and proximate result of these manufacturing defects, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

II. STRICT LIABILITY- FAILURE TO WARN

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

439. Defendants had a duty to warn Plaintiffs and Plaintiffs' physicians about the true risks and benefits of the VCDs ingested by Plaintiffs of which they knew, or in the exercise of ordinary care, should have known, at the time that the products left the Defendants' control.

440. Specifically, these Defendants should have warned Plaintiffs and Plaintiffs' physicians about the risks of ingesting NDMA, NDEA, or other nitrosamines at levels which exceeded thresholds deemed to be safe by state and federal governments throughout the United States and the rest of the world.

441. As detailed in this Complaint, these Defendants knew or should have known of many or all such risks and benefits, and yet failed to disclose them or simply misrepresented the risks and the benefits.

442. The Defendants did know, or should have known, that ingesting carcinogenic substances like NDMA, NDEA, or other nitrosamines can cause cancer.

443. These Defendants breached their duty by failing to warn Plaintiffs and their physicians of the specific risks and benefits of using their drugs.

444. Defendants, each of them, knew that the subject drugs would be prescribed by physicians like Plaintiffs' physicians and ingested by patients like Plaintiffs based upon information provided by Defendants relating to the safety and efficacy of the drugs.

445. The warnings and instructions accompanying the VCDs ingested by Plaintiffs failed to provide the level of information that an ordinarily prudent physician or consumer would expect when using the drugs in such a reasonably foreseeable manner.

446. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to use of the VCDs ingested by Plaintiffs.

447. Further, because Defendants marketed an unapproved, misbranded, and adulterated drug, Defendants failed to supply an approved warning label to Plaintiffs and Plaintiffs' physicians.

448. Plaintiffs and their physicians would not have prescribed and taken these VCDs had they known of the true safety risks related to their use.

449. As a direct and proximate result of one or more of the above-listed dangerous conditions, defects and negligence, Plaintiffs sustained serious injuries of a personal and pecuniary nature.

III. STRICT LIABILITY- DESIGN DEFECT

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

451. For the reasons described herein, the VCDs ingested by Plaintiffs were adulterated and unreasonably dangerous, as they contained carcinogenic active ingredients, namely NDMA, NDEA, and/or other nitrosamines.

452. These drugs, as intended by these Defendants, reached Plaintiffs without a substantial change in the condition in which they were sold.

453. Defendants' drugs were defectively designed because the design was unsafe for the purposes intended by Defendants (ingestion for the treatment of high blood pressure or similar indications), in the manner promoted by such Defendants and/or in a manner reasonably foreseeable by Defendants.

454. The VCDs ingested by Plaintiffs, for the uses intended by these Defendants, failed to perform as safely as an ordinary consumer would expect when used in the manner intended and marketed by them. The risks of these drugs outweighed their benefits when used for the purposes and in the manner intended and foreseeable by these Defendants.

455. These drugs were designed in a way that caused consumers to suffer injuries including, but not limited to cancer.

456. These foreseeable risks of harm could have been reduced or avoided by adopting a reasonable alternative design, as originally approved by the FDA, such as a true bioequivalent to Diovan. However, Defendants did not adopt a design that would have rendered these drugs reasonably safe.

457. Plaintiffs and Plaintiffs' physicians prescribed and took these drugs in a manner intended and reasonably foreseeable by Defendants.

458. Plaintiffs and Plaintiffs' physicians were not aware of the aforementioned defects at any time prior to the injuries caused by these drugs.

459. As a legal and proximate result of the aforementioned defects, Plaintiffs sustained the injuries and damages set forth herein.

IV. NEGLIGENCE

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

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

462. Defendants owed Plaintiffs, 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.

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

464. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiffs and Plaintiffs' physicians would use and did use their products to the detriment of Plaintiffs' health, safety and well-being.

465. As a legal and proximate result of Defendants' negligence, Plaintiffs sustained the injuries and damages set forth herein.

V. NEGLIGENCE PER SE

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

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

468. The VCDs ingested by Plaintiff 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 and Plaintiffs.

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

470. 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 VCDs to Plaintiffs and Plaintiffs' physicians.

471. 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 Plaintiff ingested these drugs, which were unreasonably dangerous.

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

473. Plaintiffs suffered, and will suffer in the future, injuries including, but not limited to physical injuries, pain, suffering, death, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment. All of these damages are permanent.

474. Plaintiff is not seeking to enforce these federal provisions in this action. Likewise, Plaintiff is not suing merely because Defendants' conduct violates these provisions. Rather Plaintiff 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.

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

476. 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.

477. Defendants' violations of these federal statutes and regulations caused Plaintiffs' injuries.

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

479. Plaintiffs are persons whom these statutes and regulations were meant to protect.

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

VI. BREACH OF EXPRESS WARRANTY

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

482. 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, and the public in such a way as to induce their purchase or use.

483. Through these representations, Defendants made express warranties that these valsartan-containing drugs would conform to the representations. More specifically, Defendants represented that these drugs, when ingested by Plaintiffs 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/or that these drugs were safe and effective to treat their conditions.

484. Defendants represented that their drugs were FDA-approved 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.

485. 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.

486. The drugs ingested by Plaintiffs 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.

487. At all relevant times, Plaintiffs took these drugs for the purpose and in the manner intended by Defendants.

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

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

490. The breach of the warranty was a substantial factor in bringing about Plaintiffs' severe and debilitating injuries, economic loss, and other damages, including but not limited to, cancer, cost of medical care, rehabilitation, lost income, cancer, pain and suffering, and mental and emotional distress for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

VII. BREACH OF IMPLIED WARRANTY

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

492. The VCDs 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.

493. At all relevant times, Plaintiffs used these products for the purpose and in the manner intended by Defendants.

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

495. Defendants breached their implied warranty to Plaintiff 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.

496. As a direct and proximate result of Defendants' acts and omissions, Plaintiff ingested these unapproved and unreasonably dangerous valsartan-containing drugs and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cancer, cost of medical care, rehabilitation, lost income, cancer, pain and suffering and great emotional and mental distress and anguish for which Plaintiffs are entitled to compensatory, special, and equitable damages in an amount to be proven at trial.

VIII. FRAUD

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

498. These Defendants had a confidential and special relationship with Plaintiffs and/or Plaintiffs' 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.

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

500. Defendants had an affirmative duty to fully and adequately warn Plaintiffs and Plaintiffs' physicians of the true health and safety risks associated with these valsartan-containing

drugs for the uses intended by these Defendants; namely, that these drugs contained unsafe levels of NDMA, NDEA, and/or other nitrosamines.

501. 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.

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

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

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

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

506. Defendants knew that Plaintiffs and Plaintiffs' physicians would regard the matters Defendants concealed and/or misrepresented to be important in determining the course of treatment for Plaintiff, including Plaintiffs and Plaintiffs' physicians' decisions regarding whether to prescribe and ingest the valsartan-containing drugs for the purposes and in the manner intended by these Defendants.

507. Defendants intended to cause Plaintiffs and Plaintiffs' 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.

508. Plaintiffs and/or Plaintiffs' physicians were justified in relying, and did rely, on Defendants' concealment of information and/or misrepresentations about the safety risks related to the VCDs in deciding to prescribe and ingest these drugs.

509. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to these unapproved and unreasonably dangerous valsartan-containing drugs and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiffs were injured and incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

IX. NEGLIGENT MISREPRESENTATION

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

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

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

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

514. Plaintiffs and/or Plaintiffs' physicians reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase these products.

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

516. 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.

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

518. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiffs suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

519. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

X. BREACH OF CONSUMER PROTECTION STATUTES

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

521. 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 valsartan-containing drugs ingested by Plaintiffs and when they falsely marketed the drugs taken by Plaintiffs as generic versions and bio-equivalents of Diovan.

522. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

523. There are no "party plaintiffs" to this Master Complaint. However, to the extent an individual by his or her attorney enters a pleading by way of adoption then it is alleged that Plaintiff is a resident of the state set forth in the pleading by way of adoption and wherever a given plaintiff resides, then that state's consumer protection law violation will be adopted by reference:

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

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

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

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

528. 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.

529. 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.

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

531. 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.

532. 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.

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

534. 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.

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

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

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

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

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

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

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

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

543. 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.

544. 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.

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

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

547. 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.

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

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

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

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

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

553. 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.

554. 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.

555. 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.

556. 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.

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

558. 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.

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

560. 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.

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

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

563. 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.

564. 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.

565. 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.

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

567. 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.

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

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

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

571. 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.

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

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

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

575. 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 valsartan-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.

576. Plaintiffs and their physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe the valsartan-containing drugs.

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

578. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

579. By reason of the foregoing, Defendants are liable to Plaintiffs under applicable law for compensatory and punitive damages to the extent available, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

XI. WRONGFUL DEATH

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

581. Decedent Plaintiffs died as a result of the Defendants' actions and the valsartan-containing drugs they designed, manufactured, labeled, marketed, packaged, distributed, and/or sold.

582. Decedents are survived by various family members, named and unnamed.

583. The representatives/administrators of Decedent Plaintiffs' estate bring this claim on behalf of the Decedent Plaintiffs' lawful heirs.

584. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love, consortium and all other damages allowed under state statutes and laws.

585. Decedent Plaintiffs' estate representative[161] brings this claim on behalf of Decedent Plaintiffs' lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

586. Decedent Plaintiffs' estate representative further pleads all wrongful death damages allowed by statue in the state or states in which the causes of action accrued.

587. By reason of the foregoing, Defendants are liable to the estates of Decedent Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

XII. SURVIVAL ACTION

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

589. As a direct and proximate result of the Defendants' wrongful conduct as outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to Decedent Plaintiffs' death.

[161] The term "estate representative" herein shall mean whichever title is deemed appropriate under applicable state law, including but not limited to, executor, personal representative, trustee, etc.

590. The representatives[162] of Decedent Plaintiffs' estates bring this claim on behalf of Decedent Plaintiffs' estates and Decedent Plaintiffs' beneficiaries for damages.

591. The representatives/administrators of Decedent Plaintiff's estate further plead all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

592. By reason of the foregoing, Defendants are liable to the estates of Decedent Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

XIII. LOSS OF CONSORTIUM

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

594. At all relevant times stated herein, Plaintiffs' spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

595. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

596. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

[162] The term "representative" herein shall mean whichever title is deemed appropriate under applicable state law, including but not limited to, executor, personal representative, trustee, etc.

597. For all Spouse Plaintiffs, Plaintiffs allege his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

598. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

599. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

600. By reason of the foregoing, Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

XIV. PUNITIVE DAMAGES

601. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

602. Defendants are under an obligation to ensure that their drugs, which were supposed to be biological equivalents to Diovan, were exactly that.

603. 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 and/or NDEA.

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

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

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

607. 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.

608. 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 Plaintiff was not valsartan, but an entirely new, unapproved, and dangerous drug.

609. 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.

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

611. 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.

612. 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.

613. 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for relief and demand judgment against Defendants, and each of them, individually, jointly and severally at trial and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. For general damages in a sum exceeding this Court's jurisdictional minimum;

C. For specific damages according to proof;

D. For all ascertainable economic and non-economic damages according to proof in a sum exceeding this Court's jurisdictional minimum;

E. For restitution and disgorgement of profits;

F. For punitive and exemplary damages according to proof;

G. For pre-judgment interest and post-judgment interest as allowed by law;

H. For reasonable attorneys' fees;

I. The costs of these proceedings; and

J. For such other and further relief as this Court deems just and proper.

Dated: 6/17/2019

Respectfully Submitted,

/s/ Ruben Honik
Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone (215) 985-9177
rhonik@golombhonik.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

/s/ Conlee Whiteley
Conlee Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel