

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

JAMES SUITS AND CYNTHIA SUITS,

Plaintiffs,

v.

ZHEJIANG HUAHAI
PHARMACEUTICAL CO., LTD.;
HUAHAI U.S., INC.; MAJOR
PHARMACEUTICALS; TEVA
PHARMACEUTICALS USA, INC.; A-S
MEDICATION SOLUTIONS, LLC;
PRINSTON PHARMACEUTICAL, INC.
D/B/A SOLCO HEALTHCARE US,
LLC.; SOLCO HEALTHCARE US,
LLC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; ACTAVIS, LLC;
BRYANT RANCH PREPACK, INC.;
REMEDYREPACK, INC.;
NORTHWIND PHARMACEUTICALS;
AVKARE, INC.; MYLAN
LABORATORIES, LTD.; MYLAN
PHARMACEUTICALS, INC.; MYLAN,
N.V.; ACTAVIS PHARMA, INC.;
CARDINAL HEALTH, INC.;
MCKESSON CORPORATION;
AMERISOURCEBERGEN
CORPORATION, H J HARKINS CO.,
INC. D/B/A PHARMA PAC, NUCARE
PHARMACEUTICALS, INC. and DOES
1-100

Defendants.

COMPLAINT AND JURY DEMAND

Civil Action No. _____

INTRODUCTION

1. Plaintiffs JAMES SUITS and CYNTHIA SUITS, by and through counsel, allege on personal knowledge 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 James Suits' development of colon cancer as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

3. 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.

NATURE OF THE ACTION

4. Plaintiffs in this action seeks compensation for injuries resulting from use of defective prescription VCDs designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

5. 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.

PARTIES

I. PLAINTIFFS

6. At all relevant times, Plaintiff James Suits resides in Copper Hill, Polk County, and is a citizen and resident of the State of Tennessee.

7. At all relevant times, Plaintiff Cynthia Suits resides in Copper Hill, Polk County,

and is a citizen and resident of the State of Tennessee.

8. 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

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

i Zhejiang Huahai Pharmaceutical Co., Ltd

9. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. 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 Eastpark Blvd., Cranbury, New Jersey 08512.

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

11. 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.¹

ii Huahai U.S., Inc.

12. Defendant Huahai U.S., Inc. is a New Jersey corporation, with its principal place of business at 2001 (and 2002) Eastpark Boulevard, Cranbury, New Jersey 08512.²

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

¹ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>; <https://www.nytimes.com/2018/07/16/health/fda-blood-pressure-valsartan.html>

² <https://www.huahaius.com/contact.html>.

iii. Major Pharmaceuticals

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

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

iv. Teva Pharmaceuticals USA, Inc.

16. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, with its principal place of business at 1090 Horsham Rd, North Wales, Pennsylvania 19454.³

17. Teva Pharmaceuticals USA manufactured VCDs under the Actavis label with API manufactured by Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.⁴

v. Teva Pharmaceutical Industries, Ltd.

18. Defendant Teva Pharmaceutical Industries, Ltd. is a foreign company incorporated and headquartered in Peta Tikvah, Israel. Teva 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, Teva has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States.

vi. A-S Medication Solutions, LLC

19. Defendant A-S Medication Solutions, LLC is a Nebraska corporation, with its principal place of business at 224 North Park Avenue, Fremont, NE 68025.⁵

20. 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 Princeton Pharmaceuticals, Inc., with the active pharmaceutical ingredient (“API”) from Defendant Zhejiang

³ <https://www.tevausa.com/Contact.aspx>.

⁴ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-issues-voluntary-nationwide-recall-valsartan-and-valsartan>.

⁵ <https://www.nebraska.gov/sos/corp/corpsearch.cgi?acct-number=10119594>

Huahai Pharmaceutical Co., Ltd.⁶

vii *Prinston Pharmaceutical, Inc.*

21. 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.

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

23. Defendant Prinston Pharmaceutical, Inc. manufactured VCDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.⁷

viii *Solco Healthcare US, LLC*

24. 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.

25. 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.

ix *RemedyRepack, Inc.*

26. Defendant RemedyRepack, Inc. is a Pennsylvania corporation, with its principal

⁶ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

⁷ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

place of business at 625 Kolter Drive, Suite 4, Indiana, PA15701.⁸

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

x. Bryant Ranch Prepack, Inc.

28. Defendant Bryant Ranch Prepack, Inc. (“Bryant Ranch”) is a California corporation with its principal place of business at 1919 N. Victory Place Burbank, CA 91504. Bryant Ranch is a repackager for the Teva and Actavis Defendants, and sold API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

xi. Northwind Pharmaceuticals

29. Defendant Northwind Pharmaceuticals is an Indiana corporation with its principal place of business at 9402 Uptown Drive, Ste. 1100, Indianapolis, IN 46256. Northwind Pharmaceuticals is also a repackager for the Teva and Actavis Defendants.

xii. Actavis Defendants

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

31. Defendant Actavis, LLC (“Actavis”) is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is Teva’s wholly

⁸ <http://www.remedyrepack.com/RemedySite2/Pages/Home.aspx>;

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

xiii. AvKARE, Inc.

32. Defendant AvKARE, Inc. is a Tennessee corporation, with its principal place of business at 615 N 1st Street, Pulaski, TN 38478-2403.⁹

33. Defendant AvKARE, Inc. serves as a repackager for the Teva and Actavis Defendants.¹⁰

xiv. H J Harkins Co., Inc. d/b/a Pharma Pac

34. Defendant H J Harkins Co., Inc. d/b/a Pharma Pac is a California corporation, with its principal place of business at 1400 West Grand Avenue, Ste. F, Grover Beach, California 93433. H J Harkins is a repackager for VCDs manufactured by Princeton Pharmaceutical, Inc., which contained API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

xv. NuCare Pharmaceuticals, Inc.

35. Defendant NuCare Pharmaceuticals, Inc. is a California corporation, with its principal place of business at 622 West Katella Avenue, Orange, California 92867. NuCare Pharmaceuticals sold adulterated and/or misbranded VCDs for Solco Healthcare U.S., LLC and Princeton Pharmaceutical, Inc., which contained API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

B. Mylan Defendants

36. 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

⁹ https://tnbear.tn.gov/Ecommerce/FilingDetail.aspx?CN=0370701172002420540951621_90_238057130083225172225.
¹⁰ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

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 generic VCDs throughout the United States.

37. Defendant Mylan N.V. (“Mylan”) is a global generic and specialty pharmaceuticals company registered in the Netherlands, with principal executive officers in Hatfield, Hertfordshire, UK and a Global Center in Canonsburg, Pennsylvania. According to Mylan’s website: “[t]he 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.

38. 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.

39. 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.

C. Wholesaler Defendants

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

41. 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.

42. 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.

43. 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.

44. As mentioned above, Defendant Cardinal Health, Inc. is a corporation, with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.¹¹

ii. McKesson Corporation

45. 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,

¹¹ <https://www.theharvarddruggroup.com/shop/contact/index>.

Texas 75039.

iii. AmerisourceBergen Corporation

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

D. Doe Defendants

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

48. Plaintiff is 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

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

50. Venue of this case is appropriate in the United States District Court for the District of New Jersey. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

PLAINTIFF'S VALSARTAN-CONTAINING MEDICATION

51. The medication in question in this case is a drug that Defendants marketed and sold under the name “valsartan.”

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

53. 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.

54. 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.

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

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

57. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012.¹²

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

¹² <https://www.forbes.com/sites/larryhusten/2012/09/25/another-one-bites-the-dust-diovan-patent-expires-but-generic-valsartan-is-mia/#4b43eaf92833>.

A. NDMA

59. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.¹³

60. According to the U.S. Environmental Protection Agency, “NDMA is a semivolatile chemical that forms in both industrial and natural processes.”¹⁴

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

62. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.¹⁵

63. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.¹⁶ 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.¹⁷

64. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.¹⁸

65. Exposure to high levels of NDMA has been linked to liver damage in humans.¹⁹

66. According to the Agency for Toxic Substances and Disease Registry, “NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one

¹³ <https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf>.

¹⁴ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

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

¹⁶ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

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

¹⁸ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

¹⁹ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding.”²⁰

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

68. 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. The statements 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.²¹

69. 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.”²²

B. NDEA

70. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.²³

71. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.²⁴

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

²⁰ https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

²¹ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

²² https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

²³ <https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf>.

²⁴ <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>.

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PLAINTIFFS’ ORIGINAL COMPLAINT

73. 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.

74. Hematological effects were also reported in animal studies.²⁵

75. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.²⁶

76. The New Jersey Department of Health notes that NDEA “should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION.”²⁷

77. 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.”²⁸

78. 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.²⁹

C. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

79. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.”³⁰

80. 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

²⁵ <https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf>.

²⁶ <https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf>.

²⁷ <https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf> (emphasis in original).

²⁸ <https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf>.

²⁹ <https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf>.

³⁰ <https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001>.

byproduct of the chemical reactions.”³¹

81. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.³²

82. Defendants Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Major Pharmaceuticals; Teva Pharmaceuticals USA, Inc.; A-S Medication Solutions, LLC; Princeton Pharmaceutical, Inc. d/b/a Solco Healthcare US, LLC.; Solco Healthcare US, LLC.; Teva Pharmaceutical Industries, Ltd.; Actavis, LLC; Bryant Ranch Prepack, Inc.; RemedyRepack, Inc.; Northwind Pharmaceuticals; AvKARE, Inc.; Mylan Laboratories, Ltd.; Mylan Pharmaceuticals, Inc.; Mylan, N.V.; Actavis Pharma, Inc.; Cardinal Health, Inc.; McKesson Corporation; AmerisourceBergen Corporation, H J Harkins Co., Inc. d/b/a Pharma Pac, NuCare Pharmaceuticals, Inc. designed, manufactured, produced, packaged, marketed, distributed and sold Valsartan contaminated with NDMA and NDEA.

D. RECALLS

83. 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 2012.³³

i. U.S. Recalls

84. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient

³¹ <https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001>.

³² www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf

³³ <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php>;
<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf>.

(API) supplied by Zhejiang Huahai Pharmaceuticals.”³⁴ FDA further noted that the valsartan-containing drugs being recalled “does not meet our safety standards.”³⁵

85. 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.”³⁶

86. 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.³⁷

87. 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.”³⁸

88. 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.”

89. 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.”³⁹

90. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow. Additional recalls were announced. However, not all prescription Valsartan was subject to recall.

91. On October 5, 2018, the FDA posted the results of some testing conducted on

³⁴ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.

³⁵ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.

³⁶ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.

³⁷ <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDER/FOIAElectronicReadingRoom/UCM621162.pdf>.

³⁸ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>.

³⁹ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

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 micrograms⁴⁰ (**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.

92. 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.⁴¹

93. 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.⁴²

94. 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

⁴⁰ <https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm>.

⁴¹ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

⁴² <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

take action to ensure the product is safe for patients.”⁴³

95. These recalls may continue past the date of the filing of this Complaint.

ii. Recalls in Other Countries

96. 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.”⁴⁴

97. 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.⁴⁵

98. 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.⁴⁶

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

99. 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.

100. NDMA and NDEA are not FDA-approved ingredients for DIOVAN, EXFORGE, or

⁴³ <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>.

⁴⁴ <https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group>.

⁴⁵ <https://www.ema.europa.eu/en/news/update-review-valsartan-medicines>.

⁴⁶ <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem>.

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.

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

102. 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.

103. 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.”⁴⁷

104. 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.

105. 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.

106. 21 C.F.R. § 211.110 contains the cGMPs regarding the “Sampling and testing of in-

⁴⁷ 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).

process materials and drug products[.]” Subsection (c) states the following:

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

21 C.F.R. § 211.110(c).

107. 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.

108. 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.

109. 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.

110. 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.

111. 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.

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

113. 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.

114. 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.

115. 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."⁴⁸

⁴⁸ <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last accessed June 5, 2019) (emphasis in original).

116. 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.⁴⁹

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

118. 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.⁵⁰

119. 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.⁵¹

II. MISBRANDED AND ADULTERATED DRUGS

120. The manufacture of any adulterated or misbranded drug is prohibited under federal

⁴⁹ <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm>.

⁵⁰ <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>.

⁵¹ <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

law.⁵²

121. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.⁵³

122. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.⁵⁴

123. 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;”⁵⁵
- 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;”⁵⁶
- 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. ...”⁵⁷
- 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.”⁵⁸

124. A drug is misbranded:

⁵² 21 U.S.C. §331(g).

⁵³ 21 U.S.C. § 331(a).

⁵⁴ 21 U.S.C. § 331(c).

⁵⁵ 21 U.S.C. § 351(a)(2)(A).

⁵⁶ 21 U.S.C. § 351(a)(2)(B).

⁵⁷ 21 U.S.C. § 351(b).

⁵⁸ 21 U.S.C. § 351(d).

- a. “If its labeling is false or misleading in any particular.”⁵⁹
- 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.”⁶⁰
- c. If the labeling does not contain, among other things, “the proportion of each active ingredient...”⁶¹
- 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. ...”⁶²
- 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.”⁶³
- f. “if it is an imitation of another drug;”⁶⁴
- g. “if it is offered for sale under the name of another drug.”⁶⁵
- 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.”⁶⁶
- i. If the drug is advertised incorrectly in any manner;⁶⁷ or

⁵⁹ 21 U.S.C. § 352(a)(1).

⁶⁰ 21 U.S.C. § 352(c).

⁶¹ 21 U.S.C. § 352(e)(1)(A)(ii).

⁶² 21 U.S.C. § 352(f).

⁶³ 21 U.S.C. § 352(g).

⁶⁴ 21 U.S.C. § 352(i)(2).

⁶⁵ 21 U.S.C. § 352(i)(3).

⁶⁶ 21 U.S.C. § 352(j).

⁶⁷ 21 U.S.C. § 352(n).

j. If the drug’s “packaging or labeling is in violation of an applicable regulation...”⁶⁸

125. 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 PLAINTIFF WAS NOT VALSARTAN, BUT NEW, UNAPPROVED, VALSARTAN-CONTAINING DRUGS

126. 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.⁶⁹

127. 21 C.F.R. § 210.3(b)(7) defines an “active ingredient” in a drug as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.”⁷⁰

128. 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.

129. 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

⁶⁸ 21 U.S.C. § 352(p).

⁶⁹ <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug>.

⁷⁰ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3>.

the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.⁷¹

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).

130. 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.*

131. 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.

132. 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.

133. Therefore, Plaintiff's state-law claims asserted herein do not conflict with the federal regulatory scheme.

134. 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.⁷² 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.

⁷¹ *See* 21 C.F.R. § 310.3(h).

⁷² <https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false>.

135. 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.

136. 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

137. 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,”⁷³ and conform to requirements governing the appearance of the label.⁷⁴

138. “Labeling” encompasses all written, printed or graphic material accompanying the drug or device,⁷⁵ and therefore broadly encompasses nearly every form of promotional activity, including not only “package inserts” but also advertising.

139. “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.”⁷⁶

140. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.⁷⁷

141. 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.

142. It is unlawful to introduce a misbranded drug into interstate commerce.⁷⁸ Thus, the

⁷³ 21 C.F.R. § 201.5.

⁷⁴ 21 C.F.R. § 801.15.

⁷⁵ *Id.* 65 Fed. Reg. 14286 (March 16, 2000).

⁷⁶ *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

⁷⁷ 21 C.F.R. § 201.6; 201.10.

⁷⁸ 21 U.S.C. § 331(a).

valsartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

VI. DEFENDANTS' FAILURE TO ADHERE TO GOOD MANUFACTURING PRACTICES

143. In manufacturing, distributing, and selling the contaminated valsartan-containing drugs ingested by Plaintiff, Defendants violated the following Current Good Manufacturing Practices.

144. Under 21 C.F.R. § 200 et seq., current good manufacturing practice (cGMP) requirements are set forth. The requirements in this part are intended to ensure that drugs will be safe and effective and otherwise in compliance with the FDCA. This part establishes basic requirements applicable to manufacturers of pharmaceutical drugs.

145. 21 C.F.R. § 201.6 states that “[t]he labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.”

146. Section 201.10 requires that all ingredients (meaning “any substance in the drug, whether added to the formulation as a single substance or in admixture [sic] with other substances) be listed. Failure to reveal the presence of an ingredient when the ingredient is material to the drug renders the drug misbranded.

147. Section 201.56 provides requirements for drug labeling:

- (1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.
- (2) The labeling must be accurate and must not be misleading.
- (3) A drug’s labeling must be based upon human data, and no claims can be

made if there is insufficient evidence of effectiveness.

148. Further, any new labels submitted to the FDA must contain all information outlined in the regulation. This includes providing adequate warnings about serious and frequently occurring adverse reactions. This also may include providing a boxed warning for adverse reactions that may lead to death or serious injury. Clinically significant adverse reactions should also be listed in the Warnings and Precautions section of the label. The label must also provide information about whether long term studies in animals have been performed to evaluate carcinogenic potential.

149. Section 202.1 covers prescription-drug advertisements and requires that the ingredients of the drug appear in advertisements. Advertisements must also contain true statements of information relating to side effects.

150. Parts 211, 225, and 266 “contain the minimum current good manufacturing practices for the methods used in, and the facilities or controls to be used for, the manufacture, processing, packaging, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that is purports or is represented to possess.” 21 CFR 210.1(a). Failure to comply with any of these regulations renders a drug adulterated. 21C.F.R. 210.1(b).

151. Section 210.3(7) defines an active ingredient in a drug: “Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.”

152. Section 211.22 requires that a quality control unit be charged with ensuring quality requirements are met and the personnel are adequately trained.

153. Sections 211.42-58 require that facilities be kept in good repair, that adequate lighting, ventilation, and temperature conditions be maintained.

154. Sections 211.100-211.115 require manufacturers to have written procedures for production and process control to ensure consistency and quality. These procedures should also require thorough documentation of any deviations from these procedures.

155. Section 211.160 require that manufacturers maintain written standards, sampling plans, test procedures, or other laboratory control mechanisms, including sampling procedures and plans, and that those standards be reviewed by a quality control unit. All deviations from these procedures should be documented.

156. Sections 211.165, 211.166, and 211.170 require that appropriate sampling and stability testing be done, and that samples be retained for testing.

157. Sections 211.180-211.198 require written records of maintenance, laboratory records, distribution records, complaint files, among other things.

158. Defendants failed to follow all of these good manufacturing practices, statutes, regulations, customs, and requirements.

PLAINTIFF'S INJURIES

159. Approximately between 2014 through 2017, Plaintiff was prescribed and took valsartan; during which Defendants' VCDs were contaminated with NDMA, NDEA, or other nitrosamines.

160. The VCDs ingested by Plaintiff were designed, manufactured, marketed, sold, or distributed by the above-captioned defendants.

161. As a result of Plaintiff's ingestion of the VCDs, Plaintiff developed and was diagnosed with colon cancer requiring hospitalizations, medical bills, medical monitoring expenses, pain and suffering, and other recoverable injuries. Thus, the consumption of the contaminated VCDs resulted in Plaintiff's permanent and disabling injuries.

162. As a result of his injury, Plaintiff has suffered significant bodily injuries, pain and suffering, mental anguish, disfigurement, inconvenience, loss of earnings and earning capacity and have and will incur past and future medical expenses.

163. Plaintiff Cynthia Suits suffered loss of consortium as a result of Plaintiff's injuries.

164. Upon information and belief, Plaintiff's prescribing physicians would not have prescribed Valsartan to Plaintiff and would have changed the way in which they treated Plaintiff's relevant conditions, but for Defendants' concealment of the true risks associated with its contaminated Valsartan.

165. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

I. CAUSATION

166. Plaintiff would not have consented to taking the VCDs at issue, had he 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, or other nitrosamines.

167. Plaintiff and his physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of the VCDs.

168. Plaintiff and his physicians did not know of the specific increased risks and serious

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dangers; or were misled by Defendants, who knew or should have known of the true risks and dangers, but consciously chose not to inform Plaintiff or his physicians of those risks, and further chose to actively misrepresent those risks and dangers to Plaintiff and his physicians.

169. Plaintiff and his 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. PLAINTIFF'S RESULTING DAMAGES AND INJURIES

170. Plaintiff 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.

171. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiff 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.

172. As a result of the use of contaminated valsartan as designed, manufactured, promoted, sold, 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. Plaintiff was injured and suffered injuries to his body and mind, the exact nature of which are not completely known to date;
- b. Plaintiff sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;
- c. Plaintiff incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages Plaintiff

suffered;

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

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

173. Plaintiff had no reason until recently to suspect that his injuries as described above was caused by Defendants' defective and unreasonably dangerous drug. Plaintiff did not know and could not have known through the exercise of reasonable diligence that the use of contaminated valsartan caused his injuries; or that his prescribed VCDs were contaminated at all. Knowledge that his VCDs were contaminated was only known after disclosure of the NDC codes of his prescriptions prior to his cancer diagnosis, which was only recently discovered. For these reasons, Plaintiff's Complaint was filed within the time period allowed by the applicable statutes of limitations.

174. Plaintiff herein brings this action within the applicable statutes of limitations. Specifically, Plaintiff brings this action within the prescribed time limits following Plaintiff's injuries, Plaintiff's knowledge of the wrongful cause and Plaintiff's discovery of the Defendants' identities. Prior to such time, Plaintiff did not know nor had reason to know of his injuries or the wrongful cause thereof or the identities of the culpable parties.

175. 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 Plaintiff herein.

176. 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

contaminated valsartan, 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 Plaintiff.

177. 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.

178. 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.

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

180. Defendants' acts and omissions, before, during and after the act causing Plaintiff's injuries, prevented his and his physicians from discovering the injury or causes thereof until recently.

181. 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 Plaintiff and other patients.

GENERAL ALLEGATIONS

182. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

183. At all relevant times, the VCDs ingested by Plaintiff were researched, developed,

manufactured, marketed, promoted, advertised, sold, designed, and distributed by Defendants.

184. Defendants negligently, carelessly, or recklessly manufactured, marketed, advertised, promoted, sold, designed, distributed the VCDs ingested by Plaintiff as safe and effective treatment for his underlying conditions.

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

186. Defendants knew or had reason to know that the VCDs ingested by Plaintiff 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.

187. Defendants promoted the VCDs ingested by Plaintiff for treatment of his high blood pressure and other indications.

188. Defendants misrepresented, downplayed, or omitted the safety risks of the VCDs ingested by Plaintiff to physicians and patients, including Plaintiff and his physicians by failing to 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.

189. Defendants willfully or intentionally failed to warn or alert physicians and patients, including Plaintiff and his physicians, of the increased risks and significant dangers resulting from the FDA-unapproved use of the VCDs ingested by her, which contained carcinogenic compounds.

190. Defendants knew or had reason to know, 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 Plaintiff and his physicians, would rely on such representations.

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

192. Defendants failed to seek FDA approval for the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiff and his physicians.

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

194. 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.

195. Defendants knew 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 Plaintiff or his physicians, preventing them from making informed choices in selecting other treatments or therapies and preventing Plaintiff and Plaintiff's physicians from timely discovering his injuries.

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

197. Defendants knew or should have known that it is the manufacturer's duty to test its products to ensure they meet quality and safety standards. Yet, Defendants failed to do so.

198. 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

COUNT 1: STRICT LIABILITY – MANUFACTURING DEFECT

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

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

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

202. At all relevant times, the medications ingested by Plaintiff containing manufacturing defects, such that they differed from the approved design and specifications of the generic drug, valsartan.

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

204. 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.”

205. 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.

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

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

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

COUNT II: STRICT LIABILITY- FAILURE TO WARN

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

210. At all relevant times, Valsartan was designed, tested, manufactured, marketed, produced, packaged, advertised, distributed and sold by Defendants in a defective and unreasonably dangerous condition.

211. Plaintiff was administered and ingested Valsartan for its intended purposes and used Valsartan in the foreseeable manner normally intended, recommended, promoted, advertised, and marketed by Defendants.

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

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

214. 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.

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

216. These Defendants breached their duty by failing to warn Plaintiff and his physicians of the specific risks and benefits of using their drugs.

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

218. The warnings and instructions accompanying the VCDs ingested by Plaintiff 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.

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

220. Further, because Defendants marketed an unapproved, misbranded, and adulterated drug, Defendants failed to supply an approved warning label to Plaintiff and his physicians.

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

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

COUNT III: STRICT LIABILITY – DESIGN DEFECT

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

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

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

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

227. The VCDs ingested by Plaintiff 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 the medications outweighed their benefits when used for the purposes and in the manner intended and foreseeable by these Defendants.

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

229. 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.

230. Plaintiff and his physicians prescribed and took these drugs in a manner intended and reasonably foreseeable by Defendants.

231. Plaintiff and his physicians were not aware of the aforementioned defects at any time prior to the injuries caused by these drugs.

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

COUNT IV: NEGLIGENCE

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

234. Defendants marketed these drugs to and for the benefit of Plaintiff.

235. Defendants owed Plaintiff and his 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.

236. Through the conduct described in this Complaint, Defendants breached their duties to Plaintiff and to Plaintiff's physicians.

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

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

COUNT V: NEGLIGENCE *PER SE*

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

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

241. 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 Plaintiff's physician and Plaintiff.

242. 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.

243. Defendants had a duty to comply with the applicable regulations.

244. Notwithstanding this duty, Defendants breached this duty by designing, manufacturing, labeling, distributing, marketing, advertising, and promoting the unapproved and unreasonably dangerous VCDs to Plaintiff and his physicians.

245. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiff's physicians prescribed, and Plaintiff ingested these drugs, which were unreasonably dangerous.

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

247. Plaintiff 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.

248. 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.

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

250. 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.

251. Defendants' violations of these federal statutes and regulations caused Plaintiff's injuries.

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

253. Plaintiff is a person whom these statutes and regulations were meant to protect.

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

COUNT VI: BREACH OF EXPRESS WARRANTY

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

256. N.J.R.S. § 12A:2-313 provides that express warranties are created by a seller through any affirmation of fact or promise made by the seller to the buyer, which relates to the goods and becomes a basis of the bargain; thereby creating an express warranty that the goods shall conform to the affirmation or promise. Defendants breached this warranty as more fully explained below.

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

258. 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 Plaintiff in the manner foreseen by Defendants, were safe and effective, that these drugs were safe and effective for use by individuals such as Plaintiff, or that these drugs were safe and effective to treat their conditions.

259. 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.

260. 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.

261. The medications ingested by Plaintiff 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.

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

263. Plaintiff and his physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its hidden increased risks and its unreasonable dangers.

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

265. The breach of the warranty was a substantial factor in bringing about Plaintiff's 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 he is entitled to compensatory and equitable damages and declaratory

relief in an amount to be proven at trial.

COUNT VII: BREACH OF IMPLIED WARRANTY

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

267. N.J.R.S. § 12A:2-314 creates a warranty that the VCDs shall be merchantable if they are sold by a seller who is a merchant with respect to goods of that kind. Defendants have sold and continue to sell goods identical to or similar to the VCDs at issue in this litigation.

268. N.J.R.S. § 12A:2-315 directs that Plaintiff, in purchasing the VCDs from Defendants, was able to rely on the Defendants' skill or judgment in selecting, selling, or furnishing suitable goods, and that those goods shall be fit for such a purpose.

269. 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.

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

271. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

272. 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.

273. 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.

COUNT VIII: FRAUD

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

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

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

277. Defendants had an affirmative duty to fully and adequately warn Plaintiff and Plaintiff's 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, or other nitrosamines.

278. 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.

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

280. Defendants fraudulently and intentionally misrepresented, or fraudulently concealed

material and important health and safety product risk information from Plaintiff and his physicians, as alleged in this Complaint.

281. Plaintiff and his 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.

282. Defendants knew that they were concealing 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, or therapies.

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

284. Defendants intended to cause Plaintiff and his physicians to rely on their concealment of information or misrepresentations about the safety risks related to these drugs to induce them to prescribe and ingest the drugs.

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

286. 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, Plaintiff was 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.

COUNT IX: NEGLIGENT MISREPRESENTATION

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

288. 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 Plaintiff.

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

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

291. Plaintiff and his physicians reasonably relied on such misrepresentations or omissions and were thereby induced to purchase these products.

292. Plaintiff and his physicians would not have purchased and used these products had they known of the true safety risks related to such use.

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

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

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

296. Plaintiffs are therefore entitled to damages in an amount to be proven at trial,

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PLAINTIFFS' ORIGINAL COMPLAINT

together with interest thereon and costs.

COUNT X: VIOLATION OF CONSUMER PROTECTION ACT

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

298. Defendants violated N.J.S.A. § 58:8, et seq. by engaging in unfair, false, misleading or deceptive acts or practices in the conduct of its business. The Defendants' failure to properly design, test, manufacture, market, and failure to warn about the contaminated VCDs constitutes a violation of New Jersey's Consumer Protection Act.

299. As more particularly described in the fact section detailed above, Defendants engaged in such conduct by wrongfully misrepresenting that the drugs they manufactured, distributed and provided to Plaintiff were safe for human consumption and were not contaminated with NDMA and/or NDEA in all the manners and methods described herein.

300. Defendants' actions were intentional and/or grossly negligent.

301. Plaintiff purchased Defendants' unsafe drugs as a result of Defendants unfair, false, misleading, or deceptive acts, and have suffered an ascertainable loss.

302. Pursuant to N.J.S.A. 56:8-13 – 18, et seq., Plaintiff is entitled to damages, attorneys' fees, actual damages, punitive damages and equitable relief.

COUNT XI: PUNITIVE DAMAGES

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

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

305. 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 or NDEA.

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

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

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

309. Defendants failed to adequately test the product they were manufacturing, marketing, distributing, repackaging, and selling to doctors and patients, like Plaintiff and his 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.

310. In marketing and selling these drugs, Defendants provided false and misleading labels to physicians and patients, including to Plaintiff and his 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.

311. 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.

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

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

314. Defendants' conduct and omissions, as set forth above, in allowing such an

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PLAINTIFFS' ORIGINAL COMPLAINT

extremely dangerous products to be used by members of the general public, including Plaintiff, constitutes fraud, malice, and oppression toward Plaintiff and others.

315. 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.

316. Plaintiffs are therefore entitled to judgment against Defendants as hereinafter set forth.

CAUSATION, DAMAGES, AND PRAYER FOR RELIEF

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

318. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been caused to suffer damages, and are entitled to equitable relief and monetary damages based on both statutory and common law violations, including but not limited to:

- 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 Plaintiffs, 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. All damages recoverable for breach of implied warranty of merchantability, breach of express warranty, and breach of implied warranty for fitness for a particular purpose;
- d. All damages allowable under N.J.S.A. § 56:8, et seq. for violation of New

Jersey's Consumer Protection Act;

- e. Actual, incidental, and foreseeable damages;
- f. Punitive damages as a result of the willful, wanton and grossly negligent conduct of the Defendants.
- g. Mental anguish;
- h. Loss of consortium;
- i. Attorneys' fees;
- j. Costs;
- k. Pre- and post-judgment interest;
- l. All equitable relief the Court may deem appropriate;

WHEREFORE, Plaintiffs, James Suits and Cynthia Suits pray to the Court as follows:

1. For a judgment against the Defendants, jointly and severally, with the Plaintiffs reserving the right to advise the trier of fact as to what amounts are fair and reasonable as shown by the evidence;
2. For a trial of this cause by a jury;
3. That Plaintiffs be awarded all of the damages enumerated above, including attorneys' fees, costs herein expended, actual, incidental, consequential, compensatory, punitive, foreseeable and any and all other damages and equitable relief that may be appropriate; and
4. Pre-judgment and post-judgment interest; and
5. Any and all other relief to which this Court may deem Plaintiffs to be entitled.

Respectfully submitted,

LOCKS LAW FIRM

/s/ Jerry Lindheim _____

Jerry Lindheim

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Cherry Hill, NJ 08034

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Facsimile: (856) 661-8400

jindheim@lockslaw.com

**COUNSEL FOR PLAINTIFFS,
JAMES SUITS AND
CYNTHIA SUITS**

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

James Suits and Cynthia Suits

(b) County of Residence of First Listed Plaintiff Polk County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Jerry A. Lindheim, Esq.
Locks Law Firm, 801 N. Kings Highway, Cherry Hill, NJ 08034
T: 856-663-8200

DEFENDANTS

Zhejiang Huahai Pharmaceutical Co., LTD; Hauahau U.S., Inc.; Major Pharmaceuticals; Teva Pharmaceuticals USA, Inc. et al.

County of Residence of First Listed Defendant Middlesex County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 2 U.S. Government Defendant
- 3 Federal Question (U.S. Government Not a Party)
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input checked="" type="checkbox"/> 4
Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	LABOR	FEDERAL TAX SUITS
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
			IMMIGRATION	
			<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from Another District (specify)
- 6 Multidistrict Litigation - Transfer
- 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. Sec. 1332

Brief description of cause:
Diversity - Pharmaceutical Injury

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____

DOCKET NUMBER _____

DATE: 05/29/2020 SIGNATURE OF ATTORNEY OF RECORD: /s/ Jerry A.Lindheim

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____