THE UNITED STATE DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In re: Valsartan NDMA Products Liability Litigation	MDL Case No. 2875 Master Docket No. 1:19-md-2875
JAMES MOSS, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.; HUAHAI U.S., INC.; PRINSTON PHARMACEUTICAL, INC. DBA SOLCO HEALTHCARE US, LLC.; SOLCO HEALTHCARE US, LLC.; WALGREENS BOOTS ALLIANCE, INC.; and DOES 1-100 Defendants.	Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge Civil Action No. 1:19-cv-14056 **COMPLAINT AND JURY DEMAND**

TABLE OF CONTENTS

INTRODUCTION

1. Plaintiff James Moss, by and through his counsel, alleges on personal knowledge as to himself, and on information and belief as to all other matters, as follows against all Defendants named herein.

2. Plaintiff James Moss brings this Complaint for his development of liver cancer, as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

3. This Complaint sets forth questions of fact and law within the context of this multidistrict proceeding for claims relating to valsartan-containing drugs ("VCDs"). It includes allegations involving products designed, manufactured, marketed, distributed, packaged, and sold by various groups of defendants. Plaintiff James Moss seeks 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 ACTIONS

4. Plaintiff James Moss 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, precursors, or byproducts.

PARTIES

I. PLAINTIFF

6. At all relevant times, Plaintiff James Moss resides in Omaha, Nebraska, and is a citizen and resident of the State of Nebraska.

7. Plaintiff James Moss 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

8. 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.

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

10. 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]

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

ii. Huahai US Inc.

11. Defendant Huahai US Inc. is a New Jersey corporation, with its principal place of business at 2001 (and 2002) Eastpark Boulevard, Cranbury, New Jersey 08512.[2]

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

iii. Prinston Pharmaceutical, Inc. dba Solco Healthcare U.S., LLC

13. Defendant Prinston Pharmaceutical, Inc., dba Solco Healthcare US, LLC[3] is a Delaware corporation, with its principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.[4]

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

15. Defendant Prinston Pharmaceutical, Inc. manufactured VCDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.[5]

iv. Solco Healthcare U.S., LLC

16. Defendant Solco Healthcare U.S., LLC is a Delaware corporation, with its principal place of business located at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512.

17. Solco Healthcare US, LLC is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, Ltd.[6]

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[2] https://www.huahaius.com/contact.html.
[3] https://www.fda.gov/Safety/Recalls/ucm613504.htm
[4] http://solcohealthcare.com/contact-us.html.
[5] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[6] http://solcohealthcare.com/about-solco.html.

18. Defendant Solco Healthcare US, LLC manufactured and/or distributed VCDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.[7]

B. Walgreens Boots Alliance, Inc.

19. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation, with its principal place of business at 108 Wilmot Road, Deerfield, Illinois.[8]

20. Defendant Walgreens Boots Alliance, Inc. sold VCDs directly to Plaintiff James Moss.

C. Does 1-100.

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

22. Plaintiff James Moss is informed and believes, and thereon alleges, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee, or joint venture of the other co-defendants and other DOE Defendants, and each of them, and at

[7] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-valsartan-and-valsartan-hctz-tablets.
[8] https://www.walgreensbootsalliance.com/contact/.

all said times, each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment, or joint venture.

JURISDICTION AND VENUE

23. 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 James Moss and the Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

24. This Court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the states where venue for each action is proper. At all relevant times Defendants transacted, solicited, and conducted business throughout the entirety of the United States and specifically in the specific jurisdictions noted by Plaintiff James Moss in this Complaint, through their employees, agents, or sales representatives, and derived substantial revenue from such business in the states where venue for each action is proper

25. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Nonetheless, Plaintiff James Moss states that but for the Order permitting direct filing into the District of New Jersey pursuant to Case Management Order No. 3, Plaintiff would have filed in the United State District Court for the District of Nebraska, where venue is also proper pursuant to 28 U.S.C. § 1391(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the State of Nebraska, in which Plaintiff James Moss resides and were injured, and they are all subject to personal jurisdiction in the District of Nebraska. Therefore, Plaintiff James Moss respectfully requests that, at the time of transfer of this action back to the trial court for further

proceedings, this case be transferred to the United State District Court for the District of Nebraska.

PLAINTIFF'S VALSARTAN-CONTAINING MEDICATION

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

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

28. 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.

29. 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.

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

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

32. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012.[9]

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

I. NDMA

34. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[10]

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

35. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[11]

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

37. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[12]

38. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[13] 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.[14]

39. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[15]

40. Exposure to high levels of NDMA has been linked to liver damage in humans.[16]

41. 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

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

one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[17]

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

43. 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.[18]

44. 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."[19]

II. NDEA.

45. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[20]

46. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[21]

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[17] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.
[18] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[21]https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[22]https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[21] 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.

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

48. 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.

49. Hematological effects were also reported in animal studies.[22]

50. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[23]

51. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[24]

52. 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."[25]

53. 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.[26]

III. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

54. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[27]

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[24] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[25] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[24] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[25] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[26] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[27] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

55. Upon information and belief, the reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions.[28]

56. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[29]

IV. RECALLS

57. 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.[30]

A. U.S. Recalls

58. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[31] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[32]

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[28] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[29] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.
[30] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php; https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[31] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[32] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

59. 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."[33]

60. 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.[34]

61. 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."[35]

62. 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."

63. 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."[36]

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

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

[33] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[34] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[35] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[36] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

levels of NDMA.[37] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[38]

66. On October 5, 2018, FDA posted the results of some testing conducted on samples of recalled valsartan tablets. Noting that "consuming up to **0.096 micrograms of NDMA per day is considered reasonably safe** for human ingestion based on lifetime exposure," the results of the testing showed levels ranging from 0.3 micrograms up to 17 micrograms[39] (emphasis added). Thus, the pills contained somewhere between 3.1 and 177 times the level of NDMA deemed reasonably safe for human consumption. Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the reasonably safe level.

67. 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.[40]

68. 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.[41]

[37] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[38] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[39] https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm.
[40] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[41] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

69. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."[42]

70. These recalls have continued through the first half of 2019.

B. Recalls in Other Countries

71. 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."[43]

72. 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.[44]

[42] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[43] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.
[44] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines.

73. 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.[45]

THE FEDERAL REGULATORY LANDSCAPE

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

74. 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."[46]

75. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an abbreviated new drug application (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 or 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.

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

[46] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (emphasis in original).

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.[47]

76. The subject drugs ingested by Plaintiff James Moss were approved by the FDA, based upon Defendants' representations that these drugs met the above criteria.

77. 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.[48]

78. 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.[49]

II. MISBRANDED AND ADULTERATED DRUGS

79. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[50]

80. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[51]

81. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[52]

82. A drug is adulterated:

[47] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm.
[48] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[49] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[50] 21 U.S.C. § 331(g).
[51] 21 U.S.C. § 331(a).
[52] 21 U.S.C. § 331(c).

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;"[53]

b. "if it is a drug and 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;"[54]

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. … No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label."[55]

d. "If it is a drug and 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."[56]

83. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[57]

[53] 21 U.S.C. § 351(a)(2)(A).
[54] 21 U.S.C. § 351(a)(2)(B).
[55] 21 U.S.C. § 351(b).
[56] 21 U.S.C. § 351(d).
[57] 21 U.S.C. § 352(a)(1).

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."[58]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[59]

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, …"[60]

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."[61]

f. "if it is an imitation of another drug;"[62]

g. "if it is offered for sale under the name of another drug."[63]

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."[64]

i. If the drug is advertised incorrectly in many manner;[65] or

[58] 21 U.S.C. § 352(c).
[59] 21 U.S.C. § 352(e)(1)(A)(ii)
[60] 21 U.S.C. § 352(f).
[61] 21 U.S.C. § 352(g).
[62] 21 U.S.C. § 352(i)(2).
[63] 21 U.S.C. § 352(i)(3).
[64] 21 U.S.C. § 352(j).
[65] 21 U.S.C. § 352(n).

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[66]

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

III. THE DRUGS INGESTED BY PLAINTIFF WERE NOT VALSARTAN, BUT NEW, UNAPPROVED, VALSARTAN-CONTAINING DRUGS

85. 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.[67]

86. 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."[68]

87. 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.

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[66] 21 U.S.C. § 352(p).

[67] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

[68] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.

88. FDA further requires that whenever a new, active ingredient is added to a drug, then the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[69]

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).

89. 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.*

90. 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.

91. 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.

92. Therefore, Plaintiff James Moss's state-law claims asserted herein do no conflict with the federal regulatory scheme.

93. 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

[69] *See* 21 C.F.R. § 310.3(h).

sale or introduction into commerce of adulterated drugs is illegal.[70] 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.

94. Plaintiff references 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.

95. Because the VCDs ingested by Plaintiff James Moss 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

96. 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,"[71] and conform to requirements governing the appearance of the label.[72]

97. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[73] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

98. "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."[74]

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[70] *See generally,* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.
[71] 21 C.F.R. § 201.5.
[72] 21 C.F.R. § 801.15.
[73] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[74] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

99. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[75]

100. Because NDMA or NDEA were not disclosed by Defendants as ingredients in the valsartan-containing drugs ingested by Plaintiff James Moss, the subject drugs were misbranded.

101. It is unlawful to introduce a misbranded drug into interstate commerce.[76] Thus, the valsartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

VI. ADHERENCE TO GOOD MANUFACTURING PRACTICES

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

103. 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.

104. 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."

105. 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)

[75] 21 C.F.R. § 201.6; 201.10.
[76] 21 U.S.C. § 331(a).

be listed. Failure to reveal the presence of an ingredient when the ingredient is material to the drug renders the drug misbranded.

106. 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.

107. 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 warnings 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.

108. 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.

109. 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 C.F.R. 210.1(a).

Failure to comply with any of these regulations renders a drug adulterated. 21 C.F.R. 210.1(b).

110. 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."

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

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

113. 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.

114. 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.

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

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

PLAINTIFF'S INJURIES

117. Approximately between August of 2016 and July of 2018, Plaintiff James Moss was prescribed and took generic valsartan; during which Defendants' VCDs were contaminated with NDMA, NDEA, or other nitrosamine compounds, precursors, or byproducts.

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

119. As a result of his ingestion of the VCDs, Plaintiff James Moss developed and was diagnosed with recurrent hepatocellular carcinoma on or around February 16, 2018, where a new 1.7 cm liver lesion was found on his imaging test, leading to his right hepatic chemoembolization and cryoablation of hepatocellular carcinoma procedures on May 8, 2018 and October 23, 2018 at University of Nebraska Medical Center, Omaha, Nebraska. Furthermore, Plaintiff James Moss is waiting for a liver transplant as a result of his liver tumor. Consequently, the consumption of the contaminated VCDs resulted in Plaintiff James Moss's permanent and disabling injuries.

I. CAUSATION

120. Plaintiff James Moss 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.

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

122. Plaintiff James Moss and his physicians did not know of the specific increased risks and serious 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.

123. Plaintiff James Moss 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

124. Plaintiff James Moss 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.

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

126. 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 James Moss suffered;

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

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

127. Plaintiff James Moss had no reason until recently to suspect that his cancer 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. For these reasons, Plaintiff James Moss's Complaint was filed within the time period allowed by the applicable statutes of limitations.

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

129. 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.

130. 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.

131. 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.

132. 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.

133. 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 James Moss, Plaintiff's physicians, and the public.

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

135. 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 James Moss and other patients.

GENERAL ALLEGATIONS

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

137. At all relevant times, the VCDs ingested by Plaintiff James Moss were researched, developed, manufactured, marketed, promoted, advertised, sold, designed, and distributed by Defendants.

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

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

140. Defendants knew or had reason to know that the VCDs ingested by Plaintiff James Moss were defective, unreasonably dangerous and not safe for human consumption, as they contained dangerously high levels of carcinogenic compounds, namely NDMA and NDEA, and other nitrosamines.

I. REPRESENTATIONS

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

142. Defendants misrepresented, downplayed, or omitted the safety risks of the VCDs ingested by Plaintiff to physicians and patients, including Plaintiff James Moss 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.

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

144. 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 James Moss and his physicians, would rely on such representations.

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

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

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

148. 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.

149. 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 James Moss and Plaintiff's physicians from timely discovering his injuries.

150. 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.

151. 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.

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

CLAIMS FOR RELIEF

I. STRICT LIABILTY- MANUFACTURING DEFECT

153. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

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

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

157. 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 James Moss.

158. 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."[77]

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

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

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

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

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

II. STRICT LIABILITY- FAILURE TO WARN

163. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

165. 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.

166. 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.

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

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

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

170. The warnings and instructions accompanying the VCDs ingested by Plaintiff James Moss 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.

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

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

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

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

III. STRICT LIABILITY- DESIGN DEFECT

175. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

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

178. 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.

179. The VCDs ingested by Plaintiff James Moss, 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.

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

181. 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.

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

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

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

IV. NEGLIGENCE

185. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

187. Defendants owed Plaintiff James Moss, 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.

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

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

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

V. NEGLIGENCE PER SE

191. Plaintiff James Moss repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

193. The VCDs ingested by Plaintiff James Moss 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.

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

195. Defendants had a duty to comply with the applicable regulations. Notwithstanding this duty, Defendants breached this duty by designing, manufacturing, labeling, distributing, marketing, advertising, and promoting the unapproved and unreasonably dangerous VCDs to Plaintiff James Moss and his physicians.

196. 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.

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

198. Plaintiff James Moss 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.

199. Plaintiff James Moss 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.

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

201. 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.

202. Defendants' violations of these federal statutes and regulations caused Plaintiff James Moss's injuries.

203. Plaintiff James Moss's injuries resulted from an occurrence that these laws and regulations were designed to prevent.

204. Plaintiff James Moss is a person whom these statutes and regulations were meant to protect.

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

VI. BREACH OF EXPRESS WARRANTY

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

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

208. 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 James Moss 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.

209. 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.

210. 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.

211. The medications ingested by Plaintiff James Moss 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.

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

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

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

215. The breach of the warranty was a substantial factor in bringing about Plaintiff James Moss'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 they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

VII. BREACH OF IMPLIED WARRANTY

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

217. 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.

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

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

220. Defendants breached their implied warranty to Plaintiff James Moss 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.

221. As a direct and proximate result of Defendants' acts and omissions, Plaintiff James Moss 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 Plaintiff James Moss is entitled to compensatory, special, and equitable damages in an amount to be proven at trial.

VIII. FRAUD

222. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

223. These Defendants had a confidential and special relationship with Plaintiff James Moss 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.

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

225. 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.

226. 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.

227. 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 James Moss 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.

228. Defendants fraudulently and intentionally misrepresented, or fraudulently concealed material and important health and safety product risk information from Plaintiff James Moss and his physicians, as alleged in this Complaint.

229. Plaintiff James Moss 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.

230. 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.

231. Defendants knew that Plaintiff James Moss and his physicians would regard the matters Defendants concealed or misrepresented to be important in determining the course of treatment for Plaintiff, including Plaintiff James Moss's 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.

232. Defendants intended to cause Plaintiff James Moss 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.

233. Plaintiff James Moss 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.

234. 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 James Moss 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.

IX. NEGLIGENT MISREPRESENTATION

235. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

236. 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 James Moss.

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

238. 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.

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

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

241. 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.

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

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

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

X. BREACH OF CONSUMER PROTECTION STATUTES

245. Plaintiff James Moss incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

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

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

248. Plaintiff James Moss is a resident of the State of Louisiana at all relevant time; consequently, Defendants' unfair competition or unfair or deceptive acts or practices constituted violations of LRA-RS 51:1401, et seq.

249. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of valsartan-containing drugs and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material

facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

250. Plaintiff and his physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize or prescribe the valsartan-containing drugs.

251. By reason of the unlawful acts engaged in by Defendants, Plaintiff James Moss have suffered ascertainable loss and damages.

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

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

XI. PUNITIVE DAMAGES

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

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

256. 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.

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

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

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

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

261. In marketing and selling these drugs, Defendants provided false and misleading labels to physicians and patients, including to Plaintiff James Moss and his physicians, which failed to disclose that the drug being prescribed to and ingested by him was not valsartan, but an entirely new, unapproved, and dangerous drug.

262. 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.

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

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

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

266. Plaintiff James Moss is 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.

267. Plaintiff James Moss is therefore entitled to judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

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

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

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

C. For specific damages according to proof;

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

E. For restitution and disgorgement of profits;

F. For punitive and exemplary damages according to proof;

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

H. For reasonable attorneys' fees;

I. The costs of these proceedings; and

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

Dated: June 20, 2019

Respectfully Submitted,

/s/ *C. Brett Vaughn*

C. Brett Vaughn
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Attorneys for Plaintiff

JS 44 (Rev. 06/17)

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

Moss, James

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
C. Brett Vaughn and Jason Chambers, Hollis Law Firm, 5100 W. 95th St., Prairie Village, KS 66207

DEFENDANTS

Zhejiang Huahai Pharmaceutical Co., Ltd.

County of Residence of First Listed Defendant Middlesex
(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
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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. Section 1332

Brief description of cause:
Products Liability Action Predicated on Ingestion of a Pharmaceutical Product

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,001.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Hon. Robert B. Kugler DOCKET NUMBER MDL 2875

DATE 06/20/2019

SIGNATURE OF ATTORNEY OF RECORD s/ C. Brett Vaughn

FOR OFFICE USE ONLY

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