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

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION JOHN FOWLER, individually and on behalf of BETTE JEAN FOWLER, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL, CO., LTD.; HUAHAI U.S. INC.; PRINSTON PHARMACEUTICAL INC.; TORRENT PHARMACEUTICALS, LTD.; TORRENT PHARMA, INC.; AND DOES 1-100, Defendants.	MDL No. 19-2875 (RBK/JS) Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge **COMPLAINT AND JURY DEMAND** Civil Action No.: 20-CV-04046

TABLE OF CONTENTS

INTRODUCTION

1. Plaintiff John Fowler, individually, and on behalf of decedent Bette Jean Fowler, by and through his counsel, allege 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 John Fowler, individually, and on behalf of decedent Bette Jean Fowler, brings this Complaint as a result of Decedents' development of Hepatocellular Carcinoma as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

NATURE OF THE ACTION

3. Plaintiff John Fowler, individually, and on behalf of decedent Bette Jean Fowler, seeks compensatory and punitive damages, monetary restitution, equitable relief, and all other available remedies compensation for injuries resulting from use of defective prescription losartan-containing drug ("LCDs") designed, manufactured, marketed, distributed, packaged, and sold by Defendants.
4. The LCDs at issue in this litigation contained impurities, including, but not limited to, N-Nitroso-dimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), or other nitrosamine compounds, precursors, or byproducts

PARTIES

I. PLAINTIFF

5. Plaintiff John Fowler currently resides in McPherson County in McPherson, Kansas; and has been at all relevant times a citizen of the state of Kansas.

6. Prior to her death, Decedent, Bette Jean Fowler, was a resident of McPherson County in McPherson, Kansas.

7. Plaintiff John Fowler is the son and natural heir of Decedent, Bette Jean Fowler.

8. Plaintiff, individually, and on behalf of decedent Bette Jean Fowler, 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 LCDs.

II. DEFENDANTS

A. Active Pharmaceutical Ingredient Manufacturers

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 and 2002 Eastpark Blvd., Cranbury, NJ 08512.

10. Zhejiang Huahai Pharmaceutical Co., Ltd. is the parent company of subsidiaries Prinston Pharmaceutical Inc. and Huahai U.S., Inc.

11. Zhejiang Huahai Pharmaceutical Co., Ltd. on its own or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, Zhejiang Huahai Pharmaceutical Co., Ltd. has been engaged in the manufacturing, sale, and distribution of adulterated or misbranded generic LCDs throughout the United States.

B. Drug Manufacturers, Labelers, and Distributors

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, NJ 08512.[1]

13. Defendant Huahai US Inc. is a wholly owned subsidiary of Defendant Zhejiang Huahai Pharmaceutical Ltd., Co. At all times material to this action, Defendant Huahai U.S., Inc. has had engaged in the manufacture, sale, distribution, and marketing of the adulterated or misbranded LCDs manufactured by Defendant Zhejiang Huahai Pharmaceutical Ltd., Co.

iii. Prinston Pharmaceutical, Inc.

14. Defendant Prinston Pharmaceutical, Inc. is a Delaware corporation, with its principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.[2]

15. Defendant Prinston Pharmaceutical, Inc. manufactured LCDs using the API manufactured by Zhejiang Huahai Pharmaceutical Co., Ltd.[3]

iv. Torrent Pharmaceuticals, Ltd.

16. Defendant Torrent Pharmaceuticals, Ltd. is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India,[4]

[1] https://www.huahaius.com/contact.html.
[2] http://solcohealthcare.com/about-us.html.
[3] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[4] http://www.torrentpharma.com/; http://www.torrentpharma.com/Index.php/site/info/contactUs

and with an international office located at: Torrent Pharma Inc., 150 Allen Road, Suite 102 Basking Ridge, NJ 07920.[5] [6]

v. Torrent Pharma, Inc.

17. Defendant Torrent Pharma, Inc. is a corporation with its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, NJ 07920.[7]

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

C. Doe Defendants

19. 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 believes, 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.

20. Plaintiff is informed and believes, and thereon allege, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee or joint venture of the

[5] http://www.torrentpharma.com/Index.php/site/info/international
[6] Complaint in Biogen International GMBH, et al. v. Torrent Pharmaceuticals LTD, et al. (District Court of Delaware 2017): https://insight.rpxcorp.com/litigation_documents/12754255
[7] http://www.torrentpharma.com/Index.php/site/info/international.

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 or joint venture.

JURISDICTION AND VENUE

21. 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 allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

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

23. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the states in which Plaintiff reside and were injured, and they are all subject to personal jurisdiction in this District. Further, this Complaint is filed in accordance with CMO 19; however, but for CMO 19, this Complaint would be properly venued in The United States District Court for the District of Kansas and may be remanded there at a future time.

THE LOSARTAN-CONTAINING DRUGS

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

25. Losartan is a generic version of the brand-name medication, Cozaar.

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

27. Losartan 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.

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

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

30. The patents for Cozaar and its various forms expired on August 11, 2009.

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

I. NDMA

32. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[8]

33. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[9]

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

[8] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.
[9] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

35. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[10]

36. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[11] 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.[12]

37. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[13]

38. Exposure to high levels of NDMA has been linked to liver damage in humans.[14]

39. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[15]

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

---

[10] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[11] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[12] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[13] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[14] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[15] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.

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

> NDMA has been found to increase the occurrence of cancer in animal studies…Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.[2]
> …
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.[16]

42. 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."[17]

II. NDEA

43. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[18]

44. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[19]

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

46. 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.

---

[16] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[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/2016-09/documents/n-nitrosodimethylamine.pdf.
[19] 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. Hematological effects were also reported in animal studies.[20]

48. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[21]

49. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[22]

50. 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."[23]

51. 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.[24]

III. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

52. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[25]

53. 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.[26]

---

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

54. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[27]

IV. RECALLS

55. 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.[28]

A. U.S. Recalls

56. 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."[29] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[30]

57. 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."[31]

58. 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.[32]

---

[27] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.
[28] *See* https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php; *see also* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[29] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[30] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[31] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[32] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.

59. 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."[33]

60. 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."

61. 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."[34]

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

63. On August 9, 2018, FDA announced that it was expending the recall to include valsartan-containing products manufactured by another API manufacturers, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained unacceptable levels of NDMA.[35] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[36]

64. 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**[37] (emphasis added). **Thus, the pills contained somewhere between 3.1 and 177 times the level of NDMA deemed reasonably safe for human consumption.**

[33] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[34] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[35] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[36] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[37] https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm.

Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the reasonably safe level.

65. 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.[38]

66. 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.[39]

67. On November 9, 2018, FDA announced the first recall of LCDs due to the presence of NDEA.

68. Additional losartan recalls continued to follow this announcement and continue through the time of the filing of this Complaint.

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

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

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."[40]

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."[41]

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.[42]

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.[43]

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,

[40] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[41] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.
[42] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines.
[43] http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem.

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."[44]

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 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.[45]

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

---

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

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

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.[46]

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.[47]

II. MISBRANDED AND ADULTERATED DRUGS

79. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[48]

80. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[49]

81. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[50]

82. A drug is adulterated:

    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;"[51]

    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;"[52]

---

[46] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[47] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[48] 21 U.S.C. § 331(g).
[49] 21 U.S.C. § 331(a).
[50] 21 U.S.C. § 331(c).
[51] 21 U.S.C. § 351(a)(2)(A).
[52] 21 U.S.C. § 351(a)(2)(B).

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. … 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."[53]

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."[54]

83. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[55]

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."[56]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[57]

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

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

application, in such manner and form, as are necessary for the protection of users, …"[58]

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."[59]

f. "if it is an imitation of another drug;"[60]

g. "if it is offered for sale under the name of another drug."[61]

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."[62]

i. If the drug is advertised incorrectly in many manner;[63] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[64]

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 LOSARTAN, BUT NEW, UNAPPROVED, LOSARTAN-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

[58] 21 U.S.C. § 352(f).
[59] 21 U.S.C. § 352(g).
[60] 21 U.S.C. § 352(i)(2).
[61] 21 U.S.C. § 352(i)(3).
[62] 21 U.S.C. § 352(j).
[63] 21 U.S.C. § 352(n).
[64] 21 U.S.C. § 352(p).

> as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[65]

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."[66]

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.

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.[67]

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.*

---

65 https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.
66 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3.
67 *See* 21 C.F.R. § 310.3(h).

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'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 sale or introduction into commerce of adulterated drugs is illegal.[68] 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 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.

95. Because the LCDs ingested by Plaintiff 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 LOSARTAN-CONTAINING DRUGS

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

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,"[69] and conform to requirements governing the appearance of the label.[70]

97. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[71] 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."[72]

99. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[73]

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

101. It is unlawful to introduce a misbranded drug into interstate commerce.[74] 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, 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

[69] 21 C.F.R. § 201.5.
[70] 21 C.F.R. § 801.15.
[71] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[72] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[73] 21 C.F.R. § 201.6; 201.10.
[74] 21 U.S.C. § 331(a).

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. § 210.1(a) states that the cCMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

105. 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."

106. 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.

107. 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.

108. 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.

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

110. 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).

111. 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."

112. Section 211.80 requires an entity to maintain procedures, in relevant part, to sample and test components and drug products, as well as to accept or reject these items for purity, strength, and quality.

113. Part 211.84 further provides, "Representative samples of each shipment of each lot shall be collected for testing or examination," and "[e]ach lot of components…shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit."

114. Specifically Section 211.90(d)(1) requires, "[a]t least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used."

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

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

117. 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.

118. 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.

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

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

PLAINTIFF'S INJURIES

121. Decedent Bette Jean Fowler was prescribed and took generic losartan during the time in which Defendants' LCDs were contaminated with NDMA, NDEA, or other nitrosamine compounds, precursors, or byproducts.

122. The LCDs ingested by Decedent were designed, manufactured, marketed, sold, or distributed by the above-captioned Defendants.

123. As a result of Decedent's ingestion of the LCDs, Decedent developed and was diagnosed with hepatocellular carcinoma, which caused permanent and disabling injuries and ultimately death to Decedent.

I. CAUSATION

124. Decedent would not have consented to taking the LCDs at issue, had Decedent 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 nitrosamine compounds, precursors, or byproducts.

125. Decedent and Decedent's physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of the LCDs.

126. Decedent and Decedent's 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 Decedent or Decedent's physicians of those risks and further chose to actively misrepresent those risks and dangers to the Decedent and Decedent's physicians.

127. Decedent and Decedent's physicians chose to take and prescribe the LCDs 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

128. Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, 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.

129. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, suffered severe injuries and damages, including but not limited to severe personal injuries, great emotional distress, and mental anguish, and ultimately death.

130. As a result of 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, individually, and on behalf of Decedent, Bette Jean Fowler, was injured and suffered injuries to body and mind, the exact nature of which are not completely known to date, include, but are not limited to the death of Bette Jean Fowler;

b. Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, 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, individually, and on behalf of Decedent, Bette Jean Fowler, incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages suffered;

d. Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, is therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

131. Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, had no reason until recently to suspect that their cancer was caused by Defendants' defective and unreasonably dangerous drug. Plaintiff, individually, and on behalf of Decedent, Bette Jean Fowler, did not know and could not have known through the exercise of reasonable diligence that the use of contaminated LCDs caused Plaintiff's injuries (or that Decedent's LCDs were contaminated at all). For these reasons, among others, Plaintiff's Complaint was filed within the time period allowed by the applicable statutes of limitations.

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

133. 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.

134. 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/Decedent.

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

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

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

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

139. 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

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

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

142. Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold, designed and/or distributed the LCDs ingested by Decedent as safe and effective treatment for Decedent s underlying conditions.

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

144. Defendants knew, and/or had reason to know, that the LCDs ingested by Decedent 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

145. Defendants designed, manufactured, labeled, marketed, packaged, distributed, and promoted the LCDs ingested by Plaintiff for treatment of high blood pressure and other indications.

146. Defendants misrepresented, downplayed, and/or omitted the safety risks of the LCDs ingested by Decedent to physicians and patients, including Decedent and Decedent's physicians by failing to identify, test for, and disclose the presence of nitrosamines in their products and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

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

148. Defendants knew and/or should have known that their representations and suggestions to physicians that their valsartan-containing drugs were safe and effective for such uses, were materially false and misleading and that physicians and patients including Decedent and Decedent's physicians, would rely on such representations.

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

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

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

152. 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.

153. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the use of the LCDs ingested by Decedent, but they concealed this information and did not warn Decedent or Decedent s physicians, preventing Decedent and Decedent s physicians from making informed choices in selecting other treatments or therapies and preventing Decedent and Decedent's physicians from timely discovering Plaintiff, individually and on behalf of Decedent, Bette Jean Fowler's injuries.

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

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

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

CLAIMS FOR RELIEF

I. STRICT LIABILITY- MANUFACTURING DEFECT

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

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

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

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

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

162. 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."[75]

163. 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.

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

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

166. As a direct and proximate result of these manufacturing defects, Plaintiff, individually and on behalf of Decedent, Bette Jean Fowler, sustained serious injuries of a personal and pecuniary nature.

II. STRICT LIABILITY- FAILURE TO WARN

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

168. Defendants had a duty to warn Decedent and Decedent's physicians about the true risks and benefits of the LCDs ingested by Decedent of which they knew, or in the exercise

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

of ordinary care, should have known, at the time that the products left the Defendants' control.

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

170. 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.

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

172. These Defendants breached their duty by failing to warn Decedent and Decedent's physicians of the specific risks and benefits of using their drugs.

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

174. The warnings and instructions accompanying the LCDs ingested by Decedent 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.

175. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to use of the LCDs ingested by Decedent.

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

177. Decedent and Decedent's physicians would not have prescribed and taken these LCDs had they known of the true safety risks related to their use.

178. As a direct and proximate result of one or more of the above-listed dangerous conditions, defects and negligence, Plaintiff, individually and on behalf of Decedent, Bette Jean Fowler, sustained serious injuries of a personal and pecuniary nature.

III. STRICT LIABILITY- DESIGN DEFECT

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

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

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

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

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

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

185. 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.

186. Decedent and Decedent's physicians prescribed and took these drugs in a manner intended and reasonably foreseeable by Defendants.

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

188. As a legal and proximate result of the aforementioned defects, Plaintiff, individually and on behalf of Decedent, Bette Jean Fowler, sustained the injuries and damages set forth herein.

IV. NEGLIGENCE

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

190. Defendants marketed these drugs to and for the benefit of Decedent.

191. Defendants owed Decedent, and Decedent's 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.

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

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

194. As a legal and proximate result of Defendants' negligence, Plaintiff, individually and on behalf of Decedent, Bette Jean Fowler, sustained the injuries and damages set forth herein.

V. NEGLIGENCE PER SE

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

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

197. The LCDs ingested by Decedent 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 Decedent's physician and Decedent.

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

199. 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 LCDs to Decedent and Decedent's physicians.

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

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

202. 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.

203. 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.

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

205. 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.

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

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

208. Plaintiff/Decedent are persons whom these statutes and regulations were meant to protect.

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

VI. BREACH OF EXPRESS WARRANTY

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

211. 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.

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

213. 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.

214. 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.

215. The drugs ingested by Decedent 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.

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

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

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

219. The breach of the warranty was a substantial factor in bringing about Plaintiff's severe and debilitating injuries, decedent's loss of life, economic loss, and other damages, including but not limited to, cancer, cost of medical care, rehabilitation, lost income, 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

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

221. The LCDs 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.

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

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

224. 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.

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

VIII. FRAUD

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

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

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

229. Defendants had an affirmative duty to fully and adequately warn Decedent and Decedent's physicians of the true health and safety risks associated with these losartan-containing drugs for the uses intended by these Defendants; namely, that these drugs contained unsafe levels of NDMA, NDEA, and/or other nitrosamines.

230. 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.

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

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

233. Decedent and/or Decedent's 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.

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

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

236. Defendants intended to cause Decedent and Decedent's physicians to rely on their concealment of information and/or misrepresentations about the safety risks related to these drugs to induce them to prescribe and ingest the drugs.

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

238. 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 were injured and incurred damages, including but not limited to medical and hospital expenses, loss of life, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

IX. NEGLIGENT MISREPRESENTATION

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

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

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

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

243. Decedent and/or Decedent's physicians reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase these products.

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

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

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

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

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

X. BREACH OF CONSUMER PROTECTION STATUTES

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

250. 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 Decedent and when they falsely marketed the drugs taken by Decedent as generic versions and bio-equivalents of Diovan.

251. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss,

pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

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

253. 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.

254. Decedent and Decedent's physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize or prescribe the valsartan-containing drugs.

255. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages, including loss of life.

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

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

XI. WRONGFUL DEATH

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

259. Decedent Bette Jean Fowler was prescribed and took generic losartan during the time in which Defendants' LCDs were contaminated with NDMA, NDEA, or other nitrosamine compounds, precursors, or byproducts.

260. Subsequent to such use, Decedent developed hepatocellular carcinoma, suffered substantial pain and suffering, both physical and emotional in nature, and subsequently died.

261. Plaintiff John Fowler is the surviving son of Decedent Bette Jean Fowler and is entitled by applicable law to bring this action.

262. Plaintiff John Fowler, on behalf of himself and all others entitled to recover for the wrongful death of Decedent, Bette Jean Fowler, is entitled to recover damages as Decedent would have if she were living, as a result of acts and/or omissions of Defendants.

263. Plaintiff, on behalf of himself and all others entitled to recover for the wrongful death of Decedent, is also entitled to recover punitive damages and damages for substantial pain and suffering caused to Decedent from the acts and/or omissions of Defendant as fully set forth herein, including without limitations, punitive damages.

264. As a direct and proximate result of Defendant's conduct, Plaintiff and Decedent have been injured catastrophically and were caused severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care and comfort, expenses for medical care and treatment, and other economic and non-economic damages.

265. Plaintiff is further entitled to recover for burial and funeral expenses; loss of protection, care, love, and companionship; and all other economic and non-economic damages.

XII. PUNITIVE DAMAGES

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

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

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

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

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

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

272. Defendants failed to adequately test the product they were manufacturing, marketing, distributing, repackaging, and selling to doctors and patients, like Decedent and Decedent's 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.

273. In marketing and selling these drugs, Defendants provided false and misleading labels to physicians and patients, including to Decedent and Decedent's physicians, which failed

to disclose that the drug being prescribed to and ingested by Decedent was not valsartan, but an entirely new, unapproved, and dangerous drug.

274. 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.

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

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

277. 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, constitutes fraud, malice, and oppression toward Plaintiff and others.

278. Plaintiff 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff 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 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 the wrongful death of decedent;

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

F. For restitution and disgorgement of profits;

G. For punitive and exemplary damages according to proof;

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

I. For reasonable attorneys' fees;

J. The costs of these proceedings; and

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

Dated: April 13, 2020

Respectfully Submitted,

PETERSON & ASSOCIATES, P.C.

/s/ Nicholas Clevenger

Nicholas S. Clevenger MO #57171
David M. Peterson MO #32229
nsc@petersonlawfirm.com
dmp@petersonlawfirm.com
801 W. 47th Street, Suite 107
Kansas City, Missouri 64112
Phone: (816) 531-4440
Fax: (816) 531-0660
ATTORNEYS FOR PLAINTIFF