UNITED STATE DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THOMAS J. PARKER, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD, HUAHAI US, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROBINDO LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., Defendants.	)	Case Docket No. 21-6130 **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

1. Plaintiff, by and through the undersigned counsel, upon information and belief, at all times hereinafter mentioned, alleges as follows:

INTRODUCTION

2. Plaintiff brings this Complaint, upon information and belief, that Plaintiff's development of multiple types of cancer resulted from taking adulterated, misbranded, and unapproved Valsartan-containing products designed, manufactured, marketed, distributed, packaged, and sold, in whole or in part, by Defendants.

PARTIES

I. PLAINTIFFS

3. At all relevant times, Plaintiff Thomas J. Parker was and is a resident of the City of New York, New York County, in the State of New York.

II. DEFENDANTS

A. Active Pharmaceutical Ingredient ("API") Manufacturers

i. Zhejiang Huahai Pharmaceutical Co., Ltd

4. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. At all times material to this case, Zhejiang has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic Valsartan in the United States, including the State of New York.

5. Defendant Huahai U.S., Inc. ("Huahai") is a New Jersey corporation located at 2009 Eastpark Blvd., Cranbury, NJ 08512. Huahai is authorized to do and doing business throughout the United States, including the State of New York. At all times material to this case, Huahai has been engaged in the manufacturing, sale, distribution of adulterated and/or misbranded generic Valsartan in the United States, including the State of New York.

6. Defendants Zhejiang and Huahai will be collectively referred to herein as "Zhejiang."

B. Valsartan-Containing Drug Manufacturers

7. Defendant Teva Pharmaceutical Industries Ltd. is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic Valsartan-containing products in the United States.

8. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly owned subsidiary of Teva.

9. Both Teva entities above will be hereinafter referred to as "Teva".

10. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic Valsartan-containing drug products in the United States.

11. Defendant Aurobindo Pharma USA, Inc was, at all relevant times, a Company doing business in the County of San Diego, State of California.

12. Defendant Aurobindo Ltd. was, at all relevant times, a Company doing business in the County of San Diego, State of California.

13. Both Aurobindo entities above will be herein after referred to as "Aurobindo."

14. At all times material to this case, Aurobindo has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic Valsartan-containing products in the United States.

JURISDICTION AND VENUE

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

16. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of New York. At all relevant times Defendants transacted, solicited, and conducted business in New York through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in New York.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because at least 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 State of New York, and they are all subject to personal jurisdiction in this District.

PLAINTIFF'S MEDICATION

18. The active ingredient in question in this case is called "Valsartan," and the drug drug products in question in this case are those that contain adulterated and/or misbranded Valsartan. Valsartan is marketed and sold either alone (aka by its brand name "Diovan") or in combination with one or more different drugs, such as, for example, amlodipine (aka by its brand name "Exforge").

19. Valsartan is the generic version of the brand-name drug Diovan.

20. Valsartan, when administered either alone or in combination with other drugs, is used to treat high blood pressure and heart failure, and to improve a patient's chances of living longer after a heart attack.

21. 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.

22. Valsartan binds to angiotensin type II receptors (AT1), working as an antagonist.

23. The patents for Diovan, Diovan/Amlodipine and Diovan/HCTZ expired in September 2012.7

24. Shortly after the patent for Diovan expired, the United States Food and Drug Administration ("FDA") began approving generic versions of these drug products to be sold in U.S. commerce.

III. NDMA

25. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.

26. According to the U.S. Environmental Protection Agency, "NDMA is a semi-volatile chemical that forms in both industrial and natural processes."

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

28. In the scientific community, NDMA is universally classified as a confirmed animal carcinogen.

29. The US Department of Health and Human Services (DHHS) similarly states that NDMA is considered 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 and administration, with tumors occurring in the esophagus, liver, respiratory tract, lung, stomach, kidney, blood vessels, and other significant parts of the body.

30. Exposure to NDMA can occur through ingestion of food, water, or medication containing high levels of nitrosamines.

31. Studies showed that over-exposure to NDMA can cause various types of cancers, including but not limited to, stomach, colorectal, intestinal, esophageal, lung, and several other types of cancers.

32. On July 27, 2018, the FDA issued a press release, explaining the reason for its concern regarding the presence of NDMA found in valsartan-containing drug products. In that statements, the FDA 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.
>
> …
>
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.

33. The Environmental Protection Agency also classified NDMA as a potential human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."

34. The U.S. National Library of Medicine says NDMA is "reasonably anticipated" to cause cancer in humans.

35. On information and belief, NDMA was formerly used in the production of, among other things, liquid rocket fuel.

36. The United States Environmental Protection Agency ("EPA") classifies NDMA as a B2 (probable human) carcinogen, based on the induction of tumors in both rodents and non-rodent mammals exposed to NDMA by various routes.

37. The World Health Organization lists NDMA as "probably carcinogenic to humans," and states that it may be released as a byproduct from municipal wastewater treatment facilities and some industrial manufacturing facilities.

38. The State of California considers NDMA and NDEA to be carcinogens and cites the National Toxicology Program as recognizing them as "reasonably anticipated to be human carcinogens."

39. Scientists use NDMA and NDEA to cause cancer in laboratory for research purposes.

40. People have used NDMA as a poison to commit murder.

IV. NDEA.

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

42. Like NDMA, NDEA is also classified as a probable human carcinogen and a well-known animal carcinogen.

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

44. NDMA is listed as a "priority toxic pollutant" in federal regulations. See 40 CFR § 131.36.

45. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can cause the formation of tumors at various parts of the human body. Animal studies have also indisputably confirmed that chronic ingestion of NDEA will cause cancer at one or more sites in the human body.

46. Hematological adverse effects have also been reported in many animal studies.

47. Tests repeatedly conducted on rats, mice, and hamsters demonstrated that NDEA can be extremely toxic through oral administration.

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

49. 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."

50. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been repeatedly shown to cause liver and gastrointestinal tract cancer, among several other types of cancers.

V. FORMATION OF NITROSAMINES IN VALSARTAN

51. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups. Such chemical groups have been well-studied, and these nitroso groups interact directly with a cell's DNA causing unwanted gene mutations.

52. Upon information and belief, the reason Defendants' manufacturing process produced unlawful amounts of NDMA and NDEA (along with other unwanted, related byproducts) is because manufacturers changed their process for making Valsartan without informing the FDA of such changes, thus having the FDA falsely believe that the Valsartan was being produced in accordance with the process originally approved by the FDA.

53. Upon information and belief, the one or more manufacture's changes in the process caused the solvents used therein to produce a tetrazole ring, such as N-Dimethylformamide (DMF), resulting in Valsartan to become toxic with the formation of accompanying drug impurities, such as NDMA and NDEA, among other undesirable, toxic byproducts of the chemical reactions to make Valsartan.

VI. FDA's RECALL OF TAINTED VALSARTAN DRUG PRODUCTS

54. Upon information and belief, the presence of excessive and dangerous levels of NDMA and NDEA in Valsartan-containing drugs is due to an unauthorized manufacturing change that took place on or around 2012, possibly earlier. Thus, such contaminated Valsartan is believed

to have been incorporated into drug products and sold in United States commerce since 2012 or earlier

55. In July 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drug products after finding excessive amounts of NDMA in the recalled products. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by a Chinese drug manufacture, Zhejiang Huahai Pharmaceuticals." FDA further noted that the recalled valsartan-containing drug products "do[] not meet our safety standards."

56. 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."

57. As of September 28, 2018, FDA essentially imposed an exclusion order on Zhejiang Huahai Pharmaceuticals Co, Ltd., effectively stopping Zhejiang from exporting any and all of its API, including Valsartan among other API's, into the United States. The FDA's punitive action resulted from its in-person inspection of Zhejiang Huahai's facility.

58. FDA's recall notice also stated that the presence of NDMA in the valsartan-containing drug products was "thought to be related to [unauthorized] changes in the way the active ingredient was manufactured."

59. The FDA extended its recall to "all lots of non-expired drug products containing any valsartan supplied by Zhejiang…"

60. On July 18, 2018, FDA issued another press release specifically about the recall of the tainted valsartan [products], emphasizing that "the recalled valsartan products pose an unnecessary risk to patients."

61. After the initial recall in July 2018, the list of valsartan-containing drug products discovered to contain tainted NDMA continued to grow significantly.

62. On August 9, 2018, FDA announced that it was further expanding the recall to include valsartan-containing products manufactured by other Valsartan suppliers, including, but

not limited to, Hetero Labs Limited, (along with its subsidiary, Camber Pharmaceuticals, Inc., as its Valsartan contained unacceptable levels of NDMA). Here, FDA found that, "Hetero Labs manufactures the [Valsartan] for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."

63. On October 5, 2018, FDA published the results of its testing on samples of recalled valsartan tablets from various generic drug companies who acquire their Valsartan API from Zhejiang. Here, FDA pointed out that "consuming up to 0.096 micrograms of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure." But, the results from testing the Valsartan tablets showed unacceptable levels of NDMA, ranging from 0.3 micrograms up to 17 micrograms. (emphasis added). Thus, the Valsartan tablets tested by FDA contained between 3.1 up to 177 times the acceptable level of NDMA deemed safe for human consumption. Subsequent testing of Valsartan tablets revealed unbelievable levels of NDMA, reaching as high as 20 micrograms per tablet, which is 208.3 times the safe level.

64. 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 drug products referenced above. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.

65. On November 21, 2018, FDA announced yet another recall because NDEA, in addition to NDMA, was detected in the tablets at unacceptable levels. At the time, the additional recall notices were only directed to unexpired valsartan-containing products.

66. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected in many other valsartan containing drug products (including those ingested by Plaintiff), as well as other ARB drugs where the FDA imposed interim limits on the amount of NDMA and NDEA that could be present to prevent shortages of Valsartan drug products. In doing so, FDA instructed "manufacturers to [develop and employ] 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."

THE FEDERAL REGULATORY LANDSCAPE

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

67. 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."

68. 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 drug 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 must be safe for human consumption .

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

e. The container in which the generic drug will be shipped and sold conforms with FDA regulations, and the generic drug's label or package insert must

be the same as the brand-name's drug label/package insert, except the brand's trademark will not appear on the genric label/package insert.

69. The subject drugs ingested by Plaintiff were approved by the FDA, based exclusively on Defendants' representations that these drugs met the above criteria and are therefore safe.

70. 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.

71. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same benefits and side effects, if any.

II. MISBRANDED AND ADULTERATED DRUGS

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

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

74. Further, the receipt in interstate commerce of any adulterated or misbranded drug is equally unlawful.

75. A drug is adulterated:

a. "If it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"

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;"

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."

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."

76. A drug is misbranded:

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

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."

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

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,

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."

f. "If it is an imitation of another drug;"

g. "If it is offered for sale under the name of another drug."

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."

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

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

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

III. THE DRUG INGESTED BY PLAINTIFF WAS NOT VALSARTAN, BUT A NEW, UNAPPROVED, VALSARTAN And VALSARTAN-CONTAINING DRUG PRODUCT

78. The FDA's website provides the definition of 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.

79. Twenty-One 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."

80. Upon information and belief, NDMA and NDEA both have the ability to cause cancer in humans by causing a genetic mutation or disruption in the DNA code, which in turn evolves into poorly differentiated cells that can form metastatic tumors as discussed above. This mutation will affect the structure or efficiency of a particular organ or section of the human body. For this reason, NDMA and NDEA are, by definition, active ingredients in a drug, albeit with potentially dire consequences.

81. 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, and approval by FDA to make and sell the drug in the U.S. Absent such FDA review and approval, the presence of unacceptable levels of NDMA and NDEA, by definition, converts what might have been an approved product into a distinct, unapproved product.

IV. FAILURE TO ADHERE TO THE CONDITIONS OF APPROVAL FOR GENERIC DRUGS, OR ALTERNATIVELY, FAILURE TO OBTAIN FDA APPROVAL FOR A NEW DRUG DEPRIVES THE MANUFACTURER OF THE PROTECTION OF FEDERAL PREEMPTION UNDER PLIVA V. MENSING, 564 U.S. 604 (2011).

82. In *Mensing*, the Supreme Court held that a state law claim which required generic manufacturers to use a different, stronger label was preempted by Federal law and FDA Regulations. *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*.

83. However, when a generic manufacturer ceases to make a drug under the terms of its approval, then the drug is not the same as its corresponding brand-name drug, in which case the generic manufacturer has unlawfully introduced an entirely new (and unapproved) drug into commerce.

84. The new and unapproved drug cannot have the same label as the brand-name drug, as the two products are no longer the same. Thus, the generic manufacturer forfeits the protection of federal preemption.

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

86. At the very least and alternatively, generic 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 The same is equally true if the brand-name drug deviates from the approval criteria for that drug. Thus, a plaintiff bringing a state-law tort claim premised upon a defendant marketing and selling an adulterated drug is not asking the manufacturer to do anything different than what federal law already requires.

87. Plaintiff's reference to federal law herein is not an 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.

88. Because Defendant's valsartan-containing drug products exceeded acceptable levels of the known carcinogens, NDMA and NDEA, Plaintiff's ingestion of these products is akin to unlawfully marketing and selling a drug that has never been approved by FDA, let alone reviewed for safety and efficacy.

V. DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF ITS VALSARTAN-CONTAINING DRUG PRODUCTS

89. Under Federal law, a drug manufacturer is required to give adequate directions for the approved use of its drug product such that a "layman can use [the][] drug safely and for the purposes for which it is intended." The product itself must also conform to the requirements governing the appearance of the label.

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

91. "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."

92. If a manufacturer labels a drug, but omits some ingredients, that renders the drug misbranded.

93. Because NDMA and/or NDEA were not disclosed by Defendants as being present in amounts well above the accepted level, the subject drugs were misbranded.

94. Introducing a misbranded drug into interstate commerce is unlawful. Thus, the valsartan-containing drug products ingested by Plaintiff were, unbeknownst to the Plaintiff, unlawfully distributed and sold.

VI. ADHERENCE TO GOOD MANUFACTURING PRACTICES REQUIRED BY LAW

95. In manufacturing, distributing, and selling the contaminated valsartan-containing drug products and then having Plaintiff ingest them, Defendants violated Good Manufacturing Practices.

96. Under 21 C.F.R. § 200 et seq., current good manufacturing practice (cGMP) requirements are set forth. These requirements are intended to ensure that drugs will be safe and effective for its intended purpose.

97. Further, 21 C.F.R. § 201.6 states that "[t]he labeling of a drug which contains two or more ingredients may be misleading because, 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."

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

99. 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.

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

101. 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, efficacy and safety.

102. Sections 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).

103. 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."

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

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

106. 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.

107. 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.

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

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

PLAINTIFF-SPECIFIC ALLEGATIONS

110. Upon information and belief, Plaintiff had been taking Valsartan-containing products from about early 2012 up to about August 2018 to treat his high blood pressure.

111. The Valsartan ingested by Plaintiff was manufactured and/or sold by the above-captioned Defendants. Plaintiff ingested adulterated and/or misbranded generic Valsartan-containing drug products in the United States conceivably every day for at least six (6) years.

112. Upon information and belief, during this time, the Valsartan-containing drug products ingested by Plaintiff were, in part, contaminated with excessive, unsafe amounts of the well-known carcinogens NDMA and NDEA.

113. Throughout the time Plaintiff continued ingesting contaminated Valsartan drug products, Plaintiff was diagnosed with various types of cancer, including:

a. Bladder Cancer (Fall 2002)

b. Skin Cancer (2006-08)

c. Testicular Cancer (May 2012)

d. Thyroid Cancer (August 2012)

e. Relapsed Testicular Cancer (Fall 2014)

f. Stage IV Squamous Cell Carcinoma (Unknown Primary)(Fall 2014)

g. Basil Cell Carcinoma on Left Eye Lid (2016)

h. Prostate Cancer (April 2021)

114. Exposure to contaminated valsartan-containing products have been linked to reports of prostate cancer, and other injuries which developed as the chemicals traveled through the digestive system.

115. Upon information and belief, the above-listed cancers resulted from Plaintiff's ingestion of Valsartan drug products contaminated with excessive and dangerous amounts of the carcinogens, NDMA and NDEA, and other toxic byproducts.

116. Plaintiff developed and was or is still being treated for each of the above listed cancers.

I. CAUSATION

117. Plaintiff would not have consented to taking any Valsartan drug product. Had Plaintiff known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drug every day for six (6) years due to the excessive amounts of the potent carcinogens, NDMA and/or NDEA in each tablet, which the FDA deemed unreasonably dangerous by the presence of these toxic chemicals.

118. Plaintiff and Plaintiff's cardiologist during the relevant time period reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of Valsartan-containing drug products.

119. Plaintiffs and Plaintiff's cardiologist did not know of the specific increased risks and serious dangers, and/or were misled by Defendants, who knew or should have known that their respective products were tainted with dangerous levels of NDMA and NDEA—known carcinogens in the science community. Instead, Defendants consciously, and with utter disregard of the patient's health, chose not to inform Plaintiffs or Plaintiff's physicians of those risks, and Defendants further chose to actively misrepresent those risks and dangers to the Plaintiff and Plaintiff's cardiologist.

120. Plaintiff and Plaintiff's cardiologist chose to take and prescribe tainted Valsartan drug products based on the risks and benefits represented to them by Defendants. Plaintiff would have made a different choice had the true risks been provided in regard to the possibility of developing potentially life-threatening cancer from contaminated Valsartan-containing drug products.

121. Upon information and belief, given that Plaintiff has had and continues to develop multiple types of cancers at an unprecedented level over the last five years or so, together with the belief that Defendants' Valsartan contained dangerous levels of the known carcinogens, NDMA and NDME as early as 2012, is indicative of the toxicity of these tainted drug, and supports the allegations herein that Plaintiff's ingestion of these carcinogenic drugs were and/or are the primary cause of Plaintiff's highly unusual proclivity to develop so many different forms of cancer.

II. PLAINTIFFS' RESULTING DAMAGES AND INJURIES

122. Plaintiff suffered serious personal, mental and physical 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.

123. Upon information and belief, as a direct and proximate result from Defendants' intentional, unlawful and irresponsible conduct, together with Plaintiff unwittingly ingesting Defendants' defective, adulterated, and cancer causing drug products for several years, Plaintiff suffered and will continue to suffer from severe injuries and damages from various cancer

treatments, including surgery and chemotherapy, as well as severe personal injuries, great emotional distress, mental anguish and loss of earning potential as a senior partner at a national law firm.

124. As a result of ingesting contaminated Valsartan drug products as designed, manufactured, promoted, sold and/or supplied by Defendants, and as a result of the gross negligence, callousness and other wrongdoings and misconduct of the Defendants as described herein:

a. Plaintiff was injured and suffered injuries to Plaintiff's 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 substantial medical expenses and other related out of pocket expenses which Plaintiff continues to incur because of the injuries and damages Plaintiff suffered to date and in the future.

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

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

125. Plaintiff had no reason to suspect that Plaintiff's 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 would cause Plaintiff's injuries (or that Plaintiff's Valsartan was contaminated at all). For these reasons, Plaintiff's Complaint was filed within the time allowed by the applicable statutes of limitations.

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

127. 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.

128. Defendants named herein are estopped from relying on any statute of limitations defense because they continued to downplay and deny reports and studies regarding the potential danger of their products. Also, Defendants' misconduct also includes: (i) denying the danger of contaminated Valsartan; (ii) actively and intentionally concealing the defects of their Valsartan products; (iii) suppressing reports and adverse information; (iv) failing to satisfy FDA and other regulatory and legal requirements; and (v) failing to disclose known dangerous defects and serious increased risks and complications to physicians and Plaintiff.

129. Defendants performed the above acts, which were and are illegal, to encourage physicians and patients to prescribe and ingest Valsartan in its contaminated and unreasonably dangerous form for long periods of time.

130. 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 Valsartan-containing drug products, particularly when the drug ceased to be the same as its brand-name counterpart.

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

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

133. Defendants' conduct was purposely committed or was at least known or should have been known by them to be dangerous. Defendants acted heedlessly, recklessly, and without regard to the consequences or the rights and safety of Plaintiff and other patients.

FURTHER ALLEGATIONS

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

135. At all relevant times, the valsartan-containing drugs ingested by Plaintiff were researched, developed, manufactured, marketed, promoted, advertised, sold, designed and/or distributed by Defendants.

136. Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold, designed and/or distributed the valsartan-containing drugs ingested by Plaintiff as safe and effective treatment for Plaintiff's underlying condition.

137. Defendants' conduct amounts to wanton, reckless, or knowing disregard of the carcinogenic substances contained in the valsartan drugs, the court said.

138. Defendants knew, and/or had reason to know, that the valsartan-containing drugs ingested by Plaintiff were defective, unreasonably dangerous, and not safe for the purposes and uses that these Defendants intended.

139. Defendants knew, and/or had reason to know, that the valsartan-containing drugs ingested by Plaintiff were defective, unreasonably dangerous and not safe for human consumption, as they contained dangerously high levels of carcinogenic compounds, namely NDMA and NDEA.

I. REPRESENTATIONS

140. Defendants promoted the valsartan-containing drugs ingested by Plaintiff for treatment of high blood pressure and other indications.

141. Defendants misrepresented, downplayed, and/or omitted the safety risks of the valsartan-containing drugs ingested by Plaintiff to physicians and patients, including Plaintiff and Plaintiff's physicians by failing to disclose the presence of NDMA and/or NDEA in their products

and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

142. Defendants willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiff and Plaintiff's physicians, of the increased risks and significant dangers resulting from the FDA-unapproved use of the valsartan-containing drugs ingested by Plaintiff, which contained excessive levels of carcinogenic compounds.

143. Defendants knew and/or had reason to know, that their representations and suggestions to physicians that their valsartan-containing drugs were safe and effective for such uses, were materially false and misleading and that physicians and patients including Plaintiff and Plaintiff's physicians, would rely on such representations.

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

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

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

147. 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.

148. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the use of the valsartan-containing drugs ingested by Plaintiff, but they concealed this information and did not warn Plaintiff or Plaintiff's physicians, preventing Plaintiff and Plaintiffs' physicians from making informed choices in selecting other treatments or therapies and preventing Plaintiff and Plaintiff's physicians from timely discovering Plaintiffs' injuries.

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

150. 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.

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

COUNTS SEEKING RELIEF

I. STRICT LIABILTY- MANUFACTURING DEFECT

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

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

154. At all relevant times, the Valsartan-containing drug products ingested by Plaintiff was expected to and did reach Plaintiff without a substantial change in its condition as manufactured, distributed, and sold by Defendants.

155. At all relevant times, the Valsartan-containing drug product ingested by Plaintiff contained manufacturing defects, in that they differed from the approved design and specifications of the generic drug, valsartan.

156. At all relevant times, the Valsartan-containing drug product ingested by Plaintiff contained manufacturing defects, in that it differed from the brand-name equivalent, thereby rendering this product unreasonably dangerous to patients such as Plaintiff.

157. Defendants were required to manufacture a drug that conformed to FDA-approved specifications, such that the drug manufactured was an equal substitute to its brand-name equivalent, Diovan, among others, which did not contain NDMA or NDEA. This drug was required 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."

158. Defendants failed to meet the requirements mentioned in the paragraph above by utilizing a flawed and unlawful manufacturing process that was unvalidated and unsafe.

159. Instead, Defendants manufactured a different drug, containing additional active and

160. At all relevant times, the Valsartan-containing drug product ingested by Plaintiff was used in a manner that was foreseeable and intended by Defendants.

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

II. STRICT LIABILITY- FAILURE TO WARN

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

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

164. Specifically, these Defendants should have warned Plaintiff and Plaintiff's physicians about the risks of ingesting NDMA and/or NDEA at levels which exceeded thresholds deemed to be safe by state and federal governments.

165. 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.

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

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

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

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

170. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to use of the valsartan-containing drugs ingested by Plaintiff.

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

172. Plaintiffs and their physicians would not have prescribed and taken these valsartan-containing drugs had they known of the true safety risks related to their use.

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

III. STRICT LIABILITY- DESIGN DEFECT

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

175. For the reasons described herein, the valsartan-containing drugs ingested by Plaintiff were adulterated and unreasonably dangerous, as they contained carcinogenic active ingredients, namely NDMA and/or NDEA.

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

177. 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.

178. The valsartan-containing drugs ingested by Plaintiff, for the uses intended by these Defendants, failed to perform as safely as an ordinary consumer would expect when used in the

manner intended and marketed by them. The risks of these drugs outweighed their benefits when used for the purposes and in the manner intended and foreseeable by these Defendants.

179. These Valsartan-containing drugs were designed in a way that caused users to suffer injuries including, but not limited to multiple advanced forms of cancer.

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

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

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

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

IV. NEGLIGENCE

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

185. Defendants marketed the Valsartan-containing drug products to and for the benefit of Plaintiff .

186. Defendants owed Plaintiff, and Plaintiff's physicians, duties to exercise reasonable or ordinary care under the circumstances considering the generally recognized and prevailing scientific knowledge at the time the products were sold.

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

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

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

V. NEGLIGENCE PER SE

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

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

192. The valsartan-containing drugs ingested by Plaintiff were designed, manufactured, sold, and distributed in violation of federal law, as these drugs never received FDA approval before being marketed and sold to Plaintiff's physician and Plaintiff.

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

194. 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 valsartan-containing drugs to Plaintiff and Plaintiff's physicians.

195. 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.

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

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

198. 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.

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

200. Thus, for violation of federal law, including the 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.

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

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

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

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

VI. BREACH OF EXPRESS WARRANTY

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

206. 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 Valsartan-containing drug products 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.

207. Through these representations, Defendants made express warranties that these valsartan-containing drug products would conform to the representations. More specifically, Defendants represented that these drugs, when ingested by Plaintiffs in the manner foreseen by Defendants, were safe and effective, that these drugs were safe and effective for use by individuals such as Plaintiff, and/or that these drugs were safe and effective to treat their conditions.

208. Defendants represented that their drugs were FDA-approved and that these drugs only contained the 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.

209. 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.

210. The drugs ingested by Plaintiff did not conform to the representations made by Defendants, because these drugs were not safe for human ingestion in the manner intended by Defendants and contained ingredients not disclosed in the product labeling.

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

212. Plaintiff and Plaintiff'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.

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

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

VII. BREACH OF IMPLIED WARRANTY

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

216. The valsartan-containing drugs 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.

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

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

219. 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.

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

VIII. FRAUD

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

222. These Defendants had a confidential and special relationship with Plaintiff and/or Plaintiff'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.

223. Upon information and belief, Defendants were aware that their drugs contained dangerous and carcinogenic compounds, namely NDMA and NDEA.

224. 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 and/or NDEA.

225. 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.

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

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

228. Plaintiffs and/or Plaintiff'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.

229. 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.

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

231. Defendants intended to cause Plaintiff and Plaintiff'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.

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

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

IX. NEGLIGENT MISREPRESENTATION

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

235. At all relevant times, Defendants were engaged in the business of manufacturing, marketing, distributing, and selling the valsartan-containing drugs for resale or use, and in fact did sell these drugs to Plaintiff.

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

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

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

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

240. 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.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants, and each of them, individually, jointly and severally at trial and requests compensatory and punitive damages as warranted, 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, chronic pain and suffering and emotional distress and anguish, for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, related out-of-pocket 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.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: July 16, 2021

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