UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

ESTATE OF PEGGY WATTS ON BEHALF OF THE ANTICIPATED PERSONAL REPRESENTATIVE AND HEIR MARY WATTS,	)	**Case No. _____**
Plaintiff	)	**JURY TRIAL DEMANDED**
v.	)	
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., PRINSTON PHARMACEUTICAL, INC. dba SOLCO HEALTHCARE US, LLC, SOLCO HEALTHCARE US, LLC, TORRENT PHARMACEUTICALS, LTD., HUAHUI U.S., INC., and DOES 1 THROUGH 100,	)	
Defendants.	)	

COMPLAINT

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INTRODUCTION

1. Plaintiff brings this Complaint as a result of Decedent Plaintiff's development of colorectal cancer, as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

PARTIES

I. PLAINTIFFS

2. At all relevant times, Decedent Plaintiff Peggy Watts was a resident of the City of Manchester, County of Coffee, in the State of Tennessee. Decedent Plaintiff Peggy Watts died on May 9, 2018 in the City of Manchester, County of Coffee, in the State of Tennessee.
3. At all relevant times, Plaintiff Mary Watts, anticipated representative and heir of the Estate of Peggy Watts, was and is a resident of the City of Manchester, County of Coffee, in the State of Tennessee.

II. DEFENDANTS

A. Active Pharmaceutical Manufacturers

i. Zhejiang Huahai Pharmaceutical Co., Ltd

4. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The company also has a United States headquarters located at 2009 Eastpark Blvd., Cranbury, NJ 08512.

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

6. The valsartan-containing drugs made by Zhejiang Huahai Pharmaceutical Co. Ltd. are distributed in the United States by three companies: Major Pharmaceuticals; Teva Pharmaceutical Industries, Ltd.; and Solco Healthcare.[1]

B. Drug Manufacturers

i. Prinston Pharmaceutical, Inc. dba Solco Healthcare US, LLC

7. Defendant Prinston Pharmaceutical, Inc., dba Solco Healthcare US, LLC[2] is a Delaware corporation, with its principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.[3]

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

ii. Solco Healthcare US, LLC

9. Defendant Solco Healthcare US, LLC is a Delware corporation, with its principal place of business located at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512.

10. Solco Healthcare US, LLC is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, Ltd.[4]

iii. Torrent Pharmaceuticals, Ltd.

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[1] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm; https://www.nytimes.com/2018/07/16/health/fda-blood-pressure-valsartan.html
[2] https://www.fda.gov/Safety/Recalls/ucm613504.htm
[3] http://solcohealthcare.com/about-us.html.
[4] http://solcohealthcare.com/about-solco.html.

11. Defendant Torrent Pharmaceuticals, Ltd. is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India,[5] and with an international office located at: Torrent Pharma Inc., 150 Allen Road, Suite 102 Basking Ridge, NJ 07920.[6] [7]

C. Other Entities

i. 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.[8]

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

ii. Does 1 through 100

14. 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 sues defendants by such fictitious names. Plaintiff is informed and believes, and thereon alleges, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Decedent 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 Decedent Plaintiff, and damages sustained by the Decedent Plaintiff. Plaintiff will

[5] http://www.torrentpharma.com/;
http://www.torrentpharma.com/Index.php/site/info/contactUs
[6] http://www.torrentpharma.com/Index.php/site/info/international
[7] 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
[8] https://www.huahaius.com/contact.html.

amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

15. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned, each of the DOE Defendants were the agents, servants, employees and/or joint venturers of the other co-defendants and other DOE Defendants, and each of them, and at all said times, each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

JURISDICTION AND VENUE

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

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

18. 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 State of Tennessee, and they are all subject to personal jurisdiction in this District.

DECEDENT PLAINTIFF'S MEDICATION

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

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

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

22. 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.

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

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

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

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

I. NDMA

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

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

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

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

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

31. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[13] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[14]

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

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

34. 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

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

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

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

36. 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.[18]

37. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[19]

II. NDEA.

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

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

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

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

41. 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.

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

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

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

45. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[25]

46. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[26]

III. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

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[21] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; *see also* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.
[22] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[23] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[24] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[25] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[26] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.

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

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

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

IV. RECALLS

50. Upon information and belief, Plaintiff states that the presence of NDMA and NDEA in the valsartan-containing drugs is due to a manufacturing change that took place on or around 2012.[30]

A. U.S. Recalls

51. 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

[27] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[28] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.
[29] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.
[30] *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.

pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[31] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[32]

52. The recall notice further stated, "Zhejiang Huahai Pharmaceuticals has stopped distributing its valsartan API and the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products."[33]

53. As of September 28, 2018, FDA placed Zhejiang Huahai Pharmaceuticals Co, Ltd. on import alerts, which halted all API made by the company from entering the United States. This was the product of an inspection of Zhejiang Huahai's facility.[34]

54. FDA's recall notice also stated that the presence of NDMA in the valsartan-containing drugs was "thought to be related to changes in the way the active substance was manufactured."[35]

55. 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."

56. On July 18, 2018, FDA put out another press release about the recall, noting its determination that "the recalled valsartan products pose an unnecessary risk to patients."[36]

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

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

58. On August 9, 2018, FDA announced that it was expanding the recall to include valsartan-containing products manufactured by another API manufacturer, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained unacceptable levels of NDMA.[37] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[38]

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

60. 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-

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

containing medications referenced above. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[40]

61. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall notices also stated that the recalls related to unexpired valsartan-containing products.[41]

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

B. Recalls in Other Countries

63. The European Medicines Agency (EMA) also recalled many batches of valsartan-containing drugs. According to the agency, "[t]he review of valsartan medicines was triggered by the European Commission on 5 July 2018…On 20 September 2018, the review was extended to include medicines containing cadesartan, Irbesartan, losartan and Olmesartan."[43]

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

64. In light of the EMA's findings, Zhejiang Huahai Pharmaceutical Co., Ltd., along with another API manufacturer, Zhejiang Tianyu, are not presently authorized to produce valsartan for medications distributed in the European Union.[44]

65. Health Canada also issued a recall of valsartan-containing medications on July 9, 2018, noting the presence of NDMA as the reason. Health Canada similarly stated that NDMA is a potential human carcinogen.[45]

THE FEDERAL REGULATORY LANDSCAPE

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

66. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[46]

67. 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:

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[44] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines.
[45] http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem.
[46] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (emphasis in original).

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.[47]

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

69. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[48]

70. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[49]

II. MISBRANDED AND ADULTERATED DRUGS

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47 https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm.

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

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

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

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

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

74. 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;"[53]

    b. "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[54]

    c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. … No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in

[50] 21 U.S.C. § 331(g).
[51] 21 U.S.C. § 331(a).
[52] 21 U.S.C. § 331(c).
[53] 21 U.S.C. § 351(a)(2)(A).
[54] 21 U.S.C. § 351(a)(2)(B).

such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label."[55]

d. "If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[56]

75. A drug is misbranded:

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

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[58]

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

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, …"[60]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[61]

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

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[55] 21 U.S.C. § 351(b).
[56] 21 U.S.C. § 351(d).
[57] 21 U.S.C. § 352(a)(1).
[58] 21 U.S.C. § 352(c).
[59] 21 U.S.C. § 352(e)(1)(A)(ii)
[60] 21 U.S.C. § 352(f).
[61] 21 U.S.C. § 352(g).
[62] 21 U.S.C. § 352(i)(2).

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

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[64]

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

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

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

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

77. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[67]

78. 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

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[63] 21 U.S.C. § 352(i)(3).
[64] 21 U.S.C. § 352(j).
[65] 21 U.S.C. § 352(n).
[66] 21 U.S.C. § 352(p).
[67] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[68]

79. 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.

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

IV. FAILURE TO ADHERE TO THE TERMS OF AN ANDA APPROVAL, OR ALTERNATIVELY, FAILURE TO OBTAIN FDA APPROVAL FOR A NEW DRUG DEPRIVES THE MANUFACTURER OF THE SHIELD OF FEDERAL PREEMPTION UNDER *PLIVA V. MENSING*, 564 U.S. 604 (2011).

81. 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.*

82. 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.

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

83. 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.

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

85. 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.[70] Thus, a plaintiff bringing a state-law tort claim premised upon this violation is not asking the manufacturer to do anything different than what federal law already requires.

86. Plaintiff references federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

87. Because the valsartan-containing drugs ingested by Decedent 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 VALSARTAN-CONTAINING DRUGS

88. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[71] and conform to requirements governing the appearance of the label.[72]

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[70] *See generally,* https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.
[71] 21 C.F.R. § 201.5.
[72] 21 C.F.R. § 801.15.

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

90. "Most, if not all, labeling is advertising. The term "labeling" is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[74]

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

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

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

VI. ADHERENCE TO GOOD MANUFACTURING PRACTICES

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

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

[73] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[74] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[75] 21 C.F.R. § 201.6; 201.10.
[76] 21 U.S.C. § 331(a).

part establishes basic requirements applicable to manufacturers of pharmaceutical drugs.

96. 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."

97. 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.

98. 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.

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.

99. 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.

100. 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).

101. 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."

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

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

104. 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.

105. 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.

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

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

PLAINTIFF-SPECIFIC ALLEGATIONS

108. Between approximately July of 2014 and February of 2018, Decedent Plaintiff Peggy Watts was prescribed and took generic valsartan to treat high blood pressure.

109. The valsartan ingested by Decedent Plaintiff was manufactured by the above-captioned defendants and was at least in part subject to the recent recall of valsartan issued by the United States Food and Drug Administration.

110. On or about March 7, 2018, Decedent Plaintiff was diagnosed with colorectal cancer.

111. As a result of Decedent Plaintiff's ingestion of contaminated valsartan, Decedent Plaintiff developed and was diagnosed with cancer, which caused permanent and disabling injuries including death. Decedent Plaintiff died from complications including cancer on May 9, 2018.

I. CAUSATION

112. Decedent Plaintiff would not have consented to taking valsartan, had Decedent Plaintiff known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drug, which was rendered unreasonably dangerous by the presence of NDMA and/or NDEA.

113. Decedent Plaintiff and her physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of valsartan.

114. Decedent Plaintiff and her physicians did not know of the specific increased risks and serious dangers, and/or were misled by Defendants, who knew or should have known of the true risks and dangers, but consciously chose not to inform Decedent Plaintiff or her physicians of those risks and further chose to actively misrepresent those risks and dangers to the Decedent Plaintiff and her physicians.

115. Decedent Plaintiff and her physicians chose to take and prescribe valsartan 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. DECEDENT PLAINTIFF'S RESULTING DAMAGES AND INJURIES

116. Decedent Plaintiff suffered serious personal injuries, including death, 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.

117. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Decedent Plaintiff suffered from severe

injuries and damages, including but not limited to severe personal injuries, great emotional distress, mental anguish, and death.

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

a. Decedent Plaintiff was injured and suffered injuries to Decedent Plaintiff's body and mind (including death), the exact nature of which are not completely known to date;

b. Decedent Plaintiff sustained economic losses, including loss of earnings, the exact amount of which is presently unknown;

c. Decedent Plaintiff incurred medical expenses as a result of the injuries and damages Decedent Plaintiff suffered;

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

III. EQUITABLE TOLLING/ FRAUDULENT CONCEALMENT

119. Plaintiff had no reason until recently to suspect that Decedent 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 caused Decedent Plaintiff's injuries (or that Decedent Plaintiff's valsartan was contaminated at all). For these reasons, Plaintiff's Complaint was filed within the time period allowed by the applicable statutes of limitations.

120. Plaintiff herein brings this action within the applicable statutes of limitations. Specifically, Plaintiff brings this action within the prescribed time limits following Decedent 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 Decedent Plaintiff's injuries and/or the wrongful cause thereof.

121. 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.

122. Defendants named herein are estopped from relying on any statute of limitations defense because they continued 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 Decedent Plaintiff.

123. Defendants performed the above acts, which were and are illegal, to encourage physicians and patients to prescribe and take valsartan in its contaminated and unreasonably dangerous form.

124. 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, particularly when the drug ceased to be the same as its brand-name counterpart.

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

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

127. 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 Decedent Plaintiff and other patients.

GENERAL ALLEGATIONS

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

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

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

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

132. Defendants knew, and/or had reason to know, that the valsartan-containing drugs ingested by Decedent 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

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

134. Defendants misrepresented, downplayed, and/or omitted the safety risks of the valsartan-containing drugs ingested by Decedent Plaintiff to physicians and patients, including Decedent Plaintiff and her 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.

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

136. 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 Decedent Plaintiff and her physicians, would rely on such representations.

137. Defendants failed to conduct proper testing relating to the unapproved drugs they manufactured, distributed, marketed, and sold to Decedent Plaintiff and her physicians.

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

139. Defendants failed to sufficiently conduct post-market surveillance for the unapproved drugs they manufactured, distributed, marketed, and sold to Decedent Plaintiff and her physicians.

140. 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.

141. 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 Decedent Plaintiff, but they concealed this information and did not warn Decedent Plaintiff or her physicians, preventing Decedent Plaintiff and her physicians from making informed choices in selecting other treatments or therapies and preventing Decedent Plaintiff and her physicians from timely discovering Decedent Plaintiff's injuries.

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

143. 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.

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

CLAIMS FOR RELIEF

I. STRICT LIABILTY- MANUFACTURING DEFECT

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

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

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

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

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

150. 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, 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."[77]

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

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

153. At all relevant times, the medication ingested by Decedent Plaintiff was used in a manner that was foreseeable and intended by Defendants.

154. As a direct and proximate result of these manufacturing defects, Decedent Plaintiff sustained serious injuries of a personal and pecuniary nature, including death.

II. STRICT LIABILITY- FAILURE TO WARN

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

156. Defendants had a duty to warn Decedent Plaintiff and her physicians about the true risks and benefits of the valsartan-containing drugs ingested by Decedent

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

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.

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

158. 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.

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

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

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

162. The warnings and instructions accompanying the valsartan-containing drugs ingested by Decedent 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.

163. 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 Decedent Plaintiff.

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

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

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

III. STRICT LIABILITY- DESIGN DEFECT

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

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

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

170. 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.

171. The valsartan-containing drugs ingested by Decedent 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.

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

173. 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.

174. Decedent Plaintiff and her physicians prescribed and took these drugs in a manner intended and reasonably foreseeable by Defendants.

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

176. As a legal and proximate result of the aforementioned defects, Decedent Plaintiff sustained the injuries and damages set forth herein, including death.

IV. NEGLIGENCE

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

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

179. Defendants owed Decedent Plaintiff, and her 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.

180. Through the conduct described in this Complaint, Defendants breached their duties to Decedent Plaintiff and her physicians.

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

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

V. NEGLIGENCE PER SE

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

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

185. The valsartan-containing drugs ingested by Decedent 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 Decedent Plaintiff's physicians and Decedent Plaintiff.

186. 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.

187. 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 Decedent Plaintiff and her physicians.

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

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

190. Decedent Plaintiff suffered injuries including, but not limited to physical injuries, pain, suffering, lost wages, disability, disfigurement, death, and legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment. All of these damages are permanent.

191. 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.

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

193. Thus, for violations 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.

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

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

196. Decedent Plaintiff was a person whom these statutes and regulations were meant to protect.

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

VI. BREACH OF EXPRESS WARRANTY

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

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

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

201. 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.

202. 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.

203. The drugs ingested by Decedent 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.

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

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

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

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

VII. BREACH OF IMPLIED WARRANTY

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

209. 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.

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

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

212. Defendants breached their implied warranty to Decedent 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.

213. As a direct and proximate result of Defendants' acts and omissions, Decedent 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, pain and suffering, great emotional and mental distress and anguish, and death, for which Plaintiff is entitled to compensatory, special, and equitable damages in an amount to be proven at trial.

VIII. FRAUD

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

215. These Defendants had a confidential and special relationship with Decedent Plaintiff and/or Decedent 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.

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

217. Defendants had an affirmative duty to fully and adequately warn Decedent Plaintiff and her 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.

218. 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.

219. 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 Decedent Plaintiff and/or her physicians. Instead, under state common law, these Defendants had a duty to fully disclose such risks and dangers to Decedent Plaintiff and/or her physicians.

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

221. Decedent Plaintiff and/or her 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.

222. 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.

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

224. Defendants intended to cause Decedent Plaintiff and her 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.

225. Decedent Plaintiff and/or her 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.

226. 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, Decedent Plaintiff was injured and incurred damages, including but not limited to medical and hospital expenses, lost wages, physical and mental pain and suffering, loss of the enjoyment of life, and death.

IX. NEGLIGENT MISREPRESENTATION

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

228. 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 Decedent Plaintiff.

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

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

231. Decedent Plaintiff and/or her physicians reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase these products.

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

233. 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.

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

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

236. 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

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

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

239. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Decedent Plaintiff suffered personal injury, economic loss, pecuniary loss, mental anguish, death, and other compensable injuries.

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

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

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

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

244. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §§1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.

245. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §§6-1-105 et seq.

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

247. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6 §§2511 et seq. and 2531 et seq.

248. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of D.C. Code Ann. §§28-3901 et seq.

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

250. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §§10-1-372 and 10-1-420.

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

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

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

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

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

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

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

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

259. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Me. Rev. Sta. Ann. tit. 5, §§205-A et seq.

260. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Code Ann., Com. Law §§13-301 et seq.

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

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

263. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of. Minn. State. §325D.44(13) et. seq. and Minn. Stat. §325F.67 621.

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

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

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

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

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

269. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. Ann. §§358-A:1 et seq.

270. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. §§56:8-1 et seq.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §§57-12-1 et seq.

272. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§349 et seq. and 350-e et seq.

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

274. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§51-12-01 et seq. and 51- 15-01 et seq.

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

276. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representation in violation of Okla. Stat. Ann. tit. 15, §§751 et seq.

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

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

279. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§6-13.1-1 et seq.

280. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Ann. §§39-5-10 et seq.

281. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§37-24-1 et seq.

282. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. §47-18-109(a)(l). The unfair and/or deceptive acts specifically include acts declared unlawful by Tenn. Code Ann. §47-18-104(b)(2), (3), (5), and (7).

283. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 et seq.

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

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

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

287. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code Ann. §§19.86.010 et seq.

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

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

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

291. 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.

292. Decedent Plaintiff and her physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe the valsartan-containing drugs.

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

294. As a direct and proximate result of Defendants' conduct, Decedent Plaintiff suffered personal injury, economic loss, pecuniary loss, mental anguish, death, and other compensable injuries.

295. 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

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

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

298. Decedent is survived by various family members, named and unnamed.

299. The representatives/administrators of Decedent Plaintiff's estate bring this claim on behalf of the Decedent Plaintiff's lawful heirs.

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

301. Decedent Plaintiff's estate representative [78] brings this claim on behalf of Decedent Plaintiff's lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

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

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

XII. SURVIVAL ACTION

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

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

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

306. The representative[79] of Decedent Plaintiff's estate brings this claim on behalf of Decedent Plaintiffs' estate and Decedent Plaintiff's beneficiaries for damages.

307. The representative/administrator of Decedent Plaintiff's estate further pleads all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

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

ADDITIONAL ALLEGATIONS SUPPORTING PUNITIVE DAMAGES

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

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

311. 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.

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

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

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

314. NDMA and NDEA have been known carcinogens for many years.

315. Further, Defendants failed to adequately test the product they were manufacturing, marketing, distributing, and selling to doctors and patients, like Decedent Plaintiff and Decedent Plaintiff'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.

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

317. 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.

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

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

320. 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

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

321. Plaintiff is therefore entitled to exemplary or punitive damages, which would serve to punish the Defendants, to deter wrongful conduct, and to encourage safer products are made in the future.

322. The punitive damages to which Plaintiff is entitled exceed the limitations codified at Tenn. Code Ann. §29-39-104.

323. The limitation on punitive damages codified at Tenn. Code Ann. §29-39-104 do not apply because of Defendants' actions.

324. The limitation on punitive damages codified at Tenn. Code Ann. §29-39-104 do not apply because such limitation violates Plaintiff's "inviolate" right to a jury trial as guaranteed by Article I, §6 of the Tennessee Constitution.

325. The limitation on punitive damages codified at Tenn. Code Ann. §29-39-104 do not apply because the limitation violates the separation of powers mandated by Article II, §§1-2 of the Tennessee Constitution.

326. The limitation on punitive damages codified at Tenn. Code Ann. §29-39-104 do not apply because the limitation violates Plaintiff's fundamental right to a full remedy, as guaranteed by Article 1, §17 of the Tennessee Constitution.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, and each of them, individually, jointly and severally at trial and requests 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 Decedent Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. Wrongful death damages allowed by statute in Tennessee;

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

D. For specific damages according to proof;

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.

Respectfully Submitted,

McKellar|Hyde, PLC

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