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GLENDA K. ROBERTSON, and WADE ROBERTSON, Plaintiffs, v. SOLCO HEALTHCARE U.S., LLC; PRINSTON PHARMACEUTICAL, INC.; HUAHAI US, INC.; ABC CORPORATIONS, ONE THROUGH TEN (said names being fictitious); JOHN DOES, ONE THROUGH TEN (said names being fictitious); Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION, MIDDLESEX COUNTY Civil Action No. **COMPLAINT AND JURY DEMAND**

Plaintiffs, Glenda and Wade Robertson, sue Defendants Solco Healthcare U.S., LLC ("Solco"), Prinston Pharmaceutical, Inc. ("Prinston"), and Huahai US, Inc. (“Huahai”). Plaintiffs make the following allegations pursuant to their investigation and best knowledge and belief:

PARTIES, JURISDICTION and VENUE

1. Plaintiff Glenda Robertson was prescribed and ingested the Defendants’ product, a valsartan-containing drug, which caused her a serious injury. At all times material to this matter, Glenda Robertson and Wade Robertson were lawfully married. Glenda Robertson and Wade Robertson are residents of the State of Tennessee.

2. Defendant Solco Healthcare U.S., LLC. ("Solco") is a limited liability company that maintains its principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, Middlesex County, New Jersey 08512. Defendant Solco can be served through its registered agent, Interstate Document Filings Inc., at 208 West State Street, Trenton, New Jersey 08608.

3. Jurisdiction and venue are proper as to Solco.

4. Solco manufactures a valsartan-containing drug.

5. Solco distributes and/or sells a valsartan-containing drug.

6. Solco markets a valsartan-containing drug.

7. Defendant Prinston Pharmaceutical, Inc. ("Prinston") is a corporation that maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, Middlesex County, New Jersey 08512. Defendant Prinston can be served through its registered agent, Interstate Document Filings Inc., at 208 West State Street, Trenton, New Jersey 08608.

8. Jurisdiction and venue are proper as to Prinston.

9. Prinston manufactures a valsartan-containing drug.

10. Prinston distributes and/or sells a valsartan-containing drug.

11. Prinston markets a valsartan-containing drug.

12. Defendant Huahai US, Inc. (“Huahai”) is a corporation organized under the laws of the State of New Jersey and maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, Middlesex County, New Jersey 08512. Defendant can be served through its registered agent, Jun Du, at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

13. Jurisdiction and venue are proper as to Huahai.

14. Huahai manufactures a valsartan-containing drug.

15. Huahai distributes and/or sells a valsartan-containing drug.

16. Huahai markets a valsartan-containing drug.

17. Defendants named in the above caption as John Doe, One through Ten (said names being fictitious, and hereinafter referred to as "John Doe") were at all relevant times, individuals who engaged in the manufacturing, marketing, sale, and/or distribution of the pharmaceutical product at issue. The identification of these individuals is not known by the plaintiffs at this time in the absence of discovery. Plaintiffs reserve the right to substitute the name(s) for those individuals designated as John Doe when and if such information becomes available.

18. Defendants named in the above caption as ABC Corporations One through Ten (said names being fictitious, and hereinafter referred to as "ABC") were at all relevant times, corporations or other jural entities that engaged in the manufacturing, marketing, sale, and/or distribution of the pharmaceutical product at issue. These corporations or other jural entities are both directly and vicariously or derivatively liable for the actionable conduct alleged herein under the theories of respondeat superior, master-servant, agency, and or right of control. The identification of these corporations or entities s not known by the plaintiffs at this time in the absence of discovery. Plaintiffs reserve the right to substitute the name(s) for those corporations or entities designated as ABC when and if such information becomes available.

19. At all times herein mentioned, each of the Defendants were the agents, servants, employees and/or joint venturers of the other co-defendants, and each of them, at all said times was acting in the full course, scope, and authority of said agency, service, employment, and/or joint venture.

20. Zhejiang Huahai Pharmaceuticals ("ZHP") is a contract manufacturer for one or more of the Defendants.

21. At all times material hereto, Defendants and ZHP acted in concert such that they are jointly and severally liable to Plaintiffs.

22. This is an action for damages that exceeds the jurisdictional limits of this Court.

INTRODUCTORY FACTS

23. Plaintiff, Glenda K. Robertson, was prescribed Valsartan on or about March 2016.

24. Valsartan, is a nonpeptide, orally active, and specific angiotensin II receptor blocker acting on the AT1 receptor subtype. It is chemically described as *N*-(1-oxopentyl)- *N*-[[2'-(1*H*-tetrazol-5-yl) [1,1'-biphenyl]-4-yl]methyl]-L-valine. Valsartan is a white to practically white fine powder. It is soluble in ethanol and methanol and slightly soluble in water. Valsartan is available as tablets for oral administration, containing 40 mg, 80 mg, 160 mg, or 320 mg of valsartan. The ingredients of the tablets include colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, iron oxides (yellow, black and/or red), magnesium, stearate, microcrystalline cellulose, polyethylene glycol 8000, and titanium dioxide.

25. There are several dosages, strengths, and distinguishing characteristics of this product as sold to customers. For a 40 mg dose, tablets are scored yellow, and the ovaloid tablets have beveled edges, imprinted NVR/DO (Side 1/Side 2); 80 mg are pale red almond- shaped tablets with beveled edges, imprinted NVR/DV; 160 mg are grey-orange almond-shaped tablets with beveled edges, imprinted NVR/DX; 320 mg are dark grey-violet almond-shaped tablets with beveled edges, imprinted NVR/DXL.

26. The label for this product states: Valsartan peak plasma concentration is reached 2 to 4 hours after dosing. Valsartan shows bi-exponential decay kinetics following intravenous administration, with an average elimination half-life of about 6 hours. Absolute bioavailability

for valsartan is about 25% (range 10%-35%). The bioavailability of the suspension (see [2.2] Dosage and Administration; Pediatric Hypertension) is 1.6 times greater than with the tablet. With the tablet, food decreases the exposure (as measured by AUC) to valsartan by about 40% and peak plasma concentration (Cmax) by about 50%. AUC and Cmax values of valsartan increase approximately linearly with increasing dose over the clinical dosing range. Valsartan does not accumulate appreciably in plasma following repeated administration. Metabolism and Elimination: Valsartan, when administered as an oral solution, is primarily recovered in feces (about 83% of dose) and urine (about 13% of dose). The recovery is mainly as unchanged drug, with only about 20% of dose recovered as metabolites. The primary metabolite, accounting for about 9% of dose, is valeryl 4-hydroxy valsartan. The enzyme(s) responsible for valsartan metabolism have not been identified but do not seem to be CYP 450 isozymes. Following intravenous administration, plasma clearance of valsartan is about 2 L/h and its renal clearance is 0.62 L/h (about 30% of total clearance). Distribution: The steady state volume of distribution of valsartan after intravenous administration is small (17 L), indicating that valsartan does not distribute into tissues extensively. Valsartan is highly bound to serum proteins (95%) mainly serum albumin.

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

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

29. The patents for Diovan and Diovan/hydrochlorothiazide expired.

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

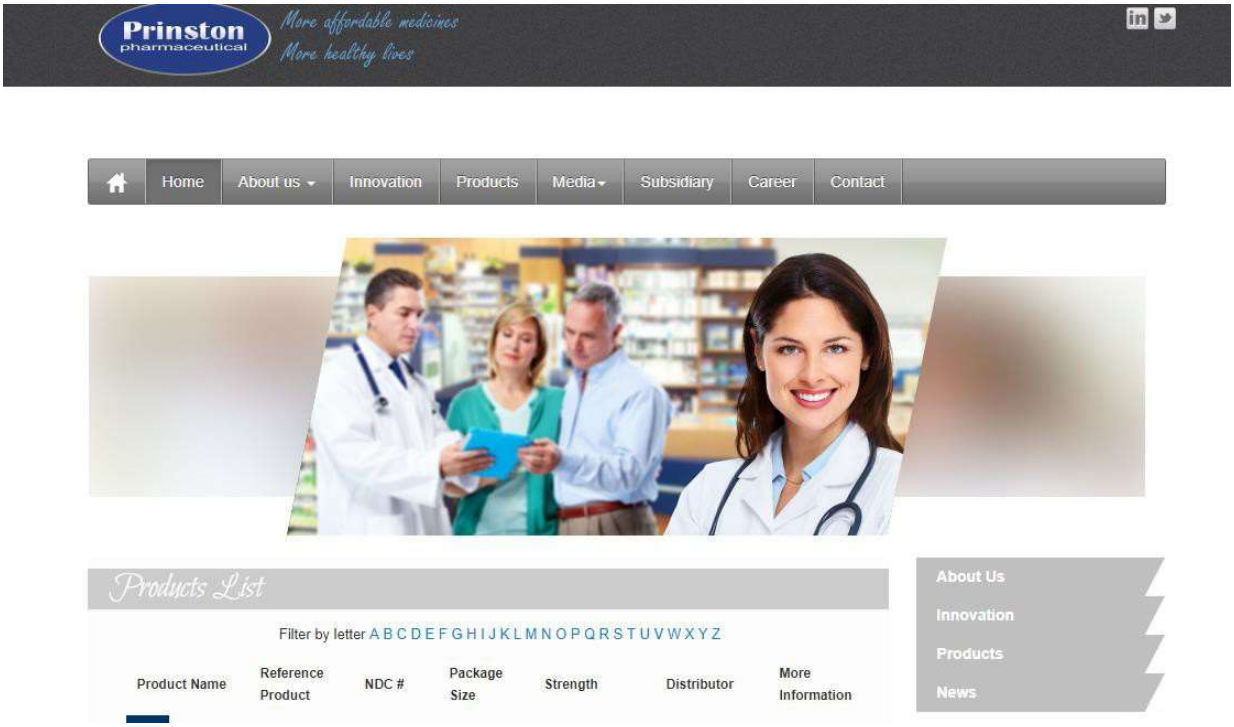
31. The valsartan-containing medication that ultimately was purchased and ingested by Plaintiff was intended for the treatment of high blood pressure.

32. Since 2013, Solco has touted its own "state of the art" manufacturing facilities, as noted on its website:

> **"Confidence in Quality:** Solco Healthcare U.S. provides state-of-the-art, FDA-approved manufacturing capabilities and a U.S. management team experienced in manufacturing and launching generic and branded pharmaceuticals, as well as orthopedic products. Solco Healthcare U.S. has the capacity to manufacture large and small volume products, shift production as necessary to produce creams, lotions, tablets, capsules, and specialty chemicals, as well as manufacture hard-to—produce and niche medications. Solco Healthcare U.S. provides business intelligence and marketing services in pharmaceutical and the life sciences. Solco Healthcare U.S. provides medical and pharmaceutical business and marketing consultation. Solco Healthcare U.S. leverages the strengths and capabilities of our world-class manufacturing facilities and our U.S. management team to bring quality generic pharmaceutical products to the U.S. market."

33. Prinston, in turn, has stated on its website that it is a fast growing, global pharmaceutical company located in Cranbury, New Jersey, USA. It tells consumers that it is a fully-integrated pharmaceutical company engaged in product development, manufacturing, marketing and sales of high quality affordable generic prescription products to its customers. Prinston tells every visitor to its website: "We deliver and maintain high quality and integrity in all of our products, which are manufactured in world-class cGMP (current Good Manufacturing Practices) manufacturing facilities." On the website for Prinston, there is a separate page for Products, which may be found here:

34. Once a website visitor navigates to the "Products List" page on the Prinston site she then is able to scroll down the page until finding information regarding valsartan on the referenced page:



35. At all times Solco, Prinston, and Huahai or its agents and representatives were directly responsible for and oversaw every step in the manufacturing process for the valsartan-containing drug for the period beginning at least as early as 2012 from the State of New Jersey.

36. ZHP serves as a contract manufacturer of some or all of Defendants' valsartan-containing products, and Defendants thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

37. Defendants have a history of deviations from FDA's cGMP standards that began almost as soon as they were approved to export pharmaceuticals to the United States.

38. On March 27-30, 2007, the FDA inspected the Linhai City facilities.[1] That inspection revealed "deviations from current good manufacturing processes (CGMP)" at the

[1] March 27-30, 2007 FDA letter is attached as Exhibit "A."

facility. Those deviations supposedly were later corrected. The results of the inspection and the steps purportedly taken subsequent to it were not made fully available to the public.

39. On May 15-19, 2017, the FDA the again inspected the Linhai City facilities where products were manufactured by the Defendants' contract manufacturer.[2] The FDA concluded that Defendants repeatedly tested out of specification ("OOS") samples until obtaining a desirable result. This practice dated back to at least September 2016. The May 2017 inspection also resulted in the FDA's finding that "impurities occurring during analytical testing are not consistently documented/quantitated[.]" These findings were not made fully available to the public.

40. During that inspection, the FDA found Defendants routinely invalidated testing results without conducting any kind of scientific investigation into the reasons behind the OOS sample result. These acts of systematic data manipulation were done to intentionally conceal the presence of harmful impurities such as NDMA.

41. N-Nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[3]

42. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[4]

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

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[2] May 15-19, 2017 inspection report is attached as Exhibit "B."
[3] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.
[4] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

44. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[5]

45. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[6] 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.[7]

46. Exposure to high levels of NDMA has been linked to liver damage in humans.[8]

47. Other studies showed an increase in other types of cancers such as stomach, bladder, colorectal, intestinal, and other digestive tract cancers.

48. 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."[9]

49. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals."[10]

50. The May 2017 inspection found that Defendants' "facilities and equipment [were] not maintained to ensure [the] quality of drug product" manufactured at the facility. These issues

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[5] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[6] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[7] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[8] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[9] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[10] https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf, p. 2.

included the FDA's finding that: equipment that was rusting and rust was being deposited into drug product; equipment was shedding cracking paint into drug product; there was an accumulation of white particulate matter; and black metallic particles found in API batches.

51. A July-August 2018 FDA Inspection[11] found Defendants' Linhai manufacturing facilities and Defendants' testing methods to be problematic in a multitude of ways, including but not limited to:

a. The change control system to evaluate all changes that may affect the production and control of intermediates or active pharmaceutical ingredient ("API") is not adequate.

b. Validation of production processes, cleaning procedures, analytical methods, and in-process control test procedures are not always adequate.

c. The system for managing quality to ensure confidence that the API will meet its intended specifications for quality and purity is not adequate … [the] quality unit lacks written procedures and the authority and responsibility to ensure all critical deviations are thoroughly investigated.

d. The quality unit does not always fulfill the responsibilities of the quality unit to release or reject all APIs.

e. Cleaning procedures do not contain sufficient details to enable operators to clean each type of equipment in a reproducible and effective manner.

f. Schedules and procedures for preventive maintenance of equipment are not adequate or do not exist.

[11] July-August 2018 inspection report is attached as Exhibit "C."

g. Substances associated with the operation of equipment, such as lubricants, heating fluids or coolants are not always food grade lubricants and oils.

h. Sampling plans, and test procedures are not always scientifically sound and appropriate to ensure raw materials, intermediates and APIs conform to established standard of quality.

i. On-going testing is not adequate.

52. Upon information and belief, Plaintiffs allege that the presence of NDMA in the valsartan-containing drugs is due to a manufacturing change that took place on or around November 2011.[12]

53. On July 12, 2018, Prinston announced via a press release that "Solco Healthcare, LLC, based in Cranbury, New Jersey" voluntarily recalled all lots of Valsartan Tablets, 40mg, 160mg, and 320mg; and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5g, 160mg/25mg, 320mg/12.5mg and 320mg/25mg, to the consumer level."

54. On July 13, 2018, the FDA announced a recall of certain batches of valsartan after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[13] FDA further noted that the valsartan being recalled "does not meet our safety standards."[14]

[12] *See* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.
[13] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[14] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

55. The recall notice further stated, defendant "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."[15]

56. The FDA's recall notice stated that the presence of NDMA in the valsartan was "thought to be related to changes in the way the active substance was manufactured"[16] by or for the defendants.

57. On July 18, 2018, FDA alerted consumers that that "the recalled valsartan products pose an unnecessary risk to patients."[17]

58. On July 27, 2018, the FDA informed consumers the reason for its concern regarding the presence of NDMA found in valsartan:

> 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.[18]
>
> …
>
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.[19]

59. As of September 28, 2018, the FDA placed defendants on import alerts, which halted all API made by the Defendants from entering the United States..[20]

60. On October 5, 2018, the FDA released results of testing conducted on samples of recalled valsartan tablets, noting that 0.096 micrograms of NDMA per day is the limits of ingestion. The results of the testing showed levels ranging from 0.3 micrograms up to 17

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[15] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[16] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[17] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[18] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm#sup2.
[19] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[20] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIA ElectronicReadingRoom/UCM621162.pdf.

micrograms.[21] The tested pills contained somewhere between 3.1 and 177 times the level of NDMA deemed the limit of human consumption. Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the limit.

61. On November 29, 2018, the FDA informed (via letter) that Defendants and their contract manufacturer had committed significant deviations from current good manufacturing practice (CGMP) involving active pharmaceutical ingredients. This FDA correspondence was directed to Jun Du, who is the Chief Executive Officer of Defendants Solco, Prinston and Huahai.[22] The FDA warning letter noted a customer complaint on September 13, 2016, where product batches that exceeded certain specifications were made, and that the batches contained NDMA which "has been classified as a probable human carcinogen."

62. By way of comparison, NDMA is sometimes also found in water and foods, including meats, dairy products, and vegetables. The UnitedStates Health Department sets strict limits on the amount of NDMA that is permitted in each category of food. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[23]

63. Plaintiff, Glenda K. Robertson, purchased and ingested the Defendants' valsartan-containing medication from approximately 2016 to 2018.

64. Plaintiff, Glenda Robertson, was injured by ingesting an acutely toxic substance, specifically NDMA, which was present in the valsartan-containing medication manufactured, tested, distributed and/or sold by Defendants. Plaintiff's injuries include the diagnosis and treatment of kidney cancer, which included the surgical removal of a tumor and a partial nephrectomy. She has incurred medical bills, lost wages, decreased ability to labor, and pain and

[21] https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm.
[22] See Attached Exhibit D.
[23] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

suffering. Each injury is permanent in nature and has greatly interfered with her enjoyment of life and her ability to carry out her chosen profession.

65. According to the 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."[24]

66. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an abbreviated new drug application (ANDA), which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

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

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[25]

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

[25] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Generic Drugs/ucm167991.htm.

67. Based upon Defendants' representations that their drugs were approved by the FDA, Plaintiff believed that the product he put in his body met the above criteria.

68. 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.[26]

69. 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.[27]

70. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[28]

71. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[29]

72. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[30]

73. 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;"[31]

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

[26] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[27] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[28] 21 U.S.C. § 331(g).
[29] 21 U.S.C. § 331(a).
[30] 21 U.S.C. § 331(c).
[31] 21 U.S.C. § 351(a)(2)(A).

safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[32]

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;"[33] or

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."[34]

74. A drug is misbranded:

a. "If its labeling is false or misleading in any particular;"[35]

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;"[36]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient;"[37]

[32] 21 U.S.C. § 351(a)(2)(B).
[33] 21 U.S.C. § 351(b).
[34] 21 U.S.C. § 351(d).
[35] 21 U.S.C. § 352(a)(1).
[36] 21 U.S.C. § 352(c).
[37] 21 U.S.C. § 352(e)(1)(A)(ii).

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... ;"[38]

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;"[39]

f. "[I]f it is an imitation of another drug;"[40]

g. "[I]f it is offered for sale under the name of another drug;"[41]

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;"[42]

i. If the drug is advertised incorrectly in any manner;[43] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[44]

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

76. The drug ingested by 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

[38] 21 U.S.C. § 352(f).
[39] 21 U.S.C. § 352(g).
[40] 21 U.S.C. § 352(i)(2).
[41] 21 U.S.C. § 352(i)(3).
[42] 21 U.S.C. § 352(j).
[43] 21 U.S.C. § 352(n).
[44] 21 U.S.C. § 352(p).

> 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.[45]

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 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."[46]

79. NDMA has the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDMA is by definition, an active ingredient 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.[47]

81. As alleged above, the drug ingested by Plaintiff was not the same as its corresponding brand-name drug; unknown to him it was an entirely new and unapproved drug.

82. Defendants made false statements in the labeling of its valsartan-containing drugs.

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[45] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.h tm#drug.

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

[47] *See* 21 C.F.R. § 310.3(h).

83. 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,"[48] and conform to requirements governing the appearance of the label.[49]

84. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[50] and, therefore, broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

85. "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."[51]

86. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[52]

87. Because NDMA was not disclosed by Defendants as an ingredient in the valsartan-containing drug ingested by Plaintiff, the subject drug was misbranded.

88. It is unlawful to introduce a misbranded drug into interstate commerce.[53] Thus, the valsartan-containing drug ingested by Plaintiff was unlawfully distributed and sold.

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

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[48] 21 C.F.R. § 201.5.
[49] 21 C.F.R. § 801.15.
[50] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[51] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).
[52] 21 C.F.R. § 201.6; 201.10.
[53] 21 U.S.C. § 331(a).

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

91. 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."

92. 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.

93. 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.

94. 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.

95. 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).

96. 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 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."

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

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

99. 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.

100. 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.

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

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

GENERAL ALLEGATIONS

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

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

105. Defendants negligently, carelessly, and/or recklessly manufactured, tested, 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.

106. 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.

107. 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 a carcinogenic compound, namely NDMA.

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

109. 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 in their product and by failing to disclose the side effects associated with ingesting this compound at dangerously high levels.

110. 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 carcinogenic compounds.

111. 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.

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

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

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

115. 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.

116. 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 Plaintiff's physicians from making informed choices in selecting other treatments or therapies and preventing Plaintiff and Plaintiff's physicians from timely discovering Plaintiff's injuries.

117. 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.

118. 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.

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

COUNT I
PRODUCT LIABILITY – MANUFACTURING DEFECT

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

121. At all times material to this action, Defendants were responsible for developing, processing, manufacturing, testing, marketing, distributing, and/or selling valsartan.

122. At all times material to this action, Defendants' valsartan containing drug was expected to reach, and did reach Plaintiff without substantial change in the condition in which it was sold.

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

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

125. 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. Diovan did not contain NDMA. 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."[54]

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

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

127. Instead, Defendants manufactured a different drug, containing at least one additional active and harmful ingredient.

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

129. Defendants, as the manufacturers and sellers of the valsartan-containing drug, had a duty to Glenda Robertson and her physicians to manufacture, test, advertise, promote, market, distribute, and/or sell a product that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.

130. At all times material to this action the valsartan-containing drug was processed, manufactured, tested, advertised, promoted, marketed, distributed, and/or sold in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars. When placed in the stream of commerce, Defendants' valsartan-containing drug contained manufacturing defects, which rendered the product unreasonably dangerous for its intended use.

131. The valsartan-containing drug's manufacturing defects occurred while the product was in the possession and control of Defendants.

132. The valsartan-containing drug 's manufacturing defects existed before it left the control of the Defendants.

133. Plaintiff would not have consented to taking valsartan had 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.

134. Plaintiff and Plaintiff's physicians reasonably relied on Defendant's representations and omissions regarding the safety and efficacy of the valsartan-containing drug.

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

136. Plaintiff and Plaintiff's physicians chose to take and prescribe Defendants' valsartan-containing drug based on the risks and benefits disclosed to them by Defendants but would have made a different choice, had the true risks and benefits been provided.

137. As a direct and proximate result of the valsartan-containing drug 's manufacturing defects, Plaintiff, Glenda Robertson, sustained and will continue to sustain damages in the future, including, but not limited to past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future.

WHEREFORE, Plaintiffs pray for judgment in Count I against Defendants for damages for past, present and future.

COUNT II
STRICT LIABILITY

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

139. Defendants are engaged in the business of manufacturing, testing, marketing, distributing and/or selling the valsartan-containing drug ingested by Plaintiff Glenda Robertson.

140. At the time it was sold by defendants, the valsartan-containing drug was in a defective condition and unreasonably dangerous to persons such as Plaintiff Glenda Robertson when put to a reasonably anticipated use because it contained NDMA, a known carcinogen.

141. The valsartan-containing drug ingested by Plaintiff Glenda Robertson was expected to reach and did reach the hands of plaintiff without substantial change in the condition in which it was manufactured and sold.

142. The valsartan-containing drug sold by Defendants was used in a manner reasonably anticipated.

143. Defendants knew or should have known the valsartan-containing drug contained NDMA at the time the medication was placed into the stream of commerce.

144. The valsartan-containing drug ingested by Plaintiff Glenda Robertson and sold by Defendants was the direct and proximate cause of Plaintiff Glenda Robertson's damages, all as more fully described herein.

145. Defendants knew when they manufactured, tested, marketed, distributed and/or sold the medication that it was intended for consumption by members of the public.

WHEREFORE, Plaintiffs pray for judgment in Count II against Defendants for damages for past, present and future.

COUNT III
NEGLIGENCE

PRODUCT LIABILITY – NEGLIGENCE

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

147. Defendants owed a duty of ordinary care to Plaintiffs to manufacture, test, market, distribute and sell the subject valsartan medication free from harmful defects and impurities.

148. Plaintiff Glenda Robertson used the valsartan-containing drug in a manner reasonably anticipated by Defendants.

149. Defendants breached their duty of ordinary care by failing to act as a reasonably careful manufacturer or distributor/seller when manufacturing, testing, marketing, distributing, and selling the medication contaminated with NDMA by failing to conduct a reasonable inspection of the product to ensure it was free of harmful impurities and/or defects; ensure that the manufacturing processes would not produce results in the composition of the medication that would render the medication harmful to humans; and evaluate the effects of the manufacturing process to ensure the product would be free of harmful defects and impurities.

150. As a direct and proximate result of Defendants' negligence, Plaintiff, Glenda Robertson, was injured, as more fully set forth herein, by ingesting an acutely toxic substance, specifically NDMA, which was negligently present in the valsartan-containing drug manufactured, tested, distributed and/or sold by Defendants.

151. Defendants knew or should have known the product contained NDMA at the time the product was placed into the stream of commerce.

152. Defendants knew when they manufactured, distributed and/or sold the medication that it was intended for consumption by members of the public.

WHEREFORE, Plaintiffs pray for judgment in Count III against Defendants for damages for past, present and future.

COUNT IV
NEGLIGENCE PER SE

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

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

155. The valsartan-containing drugs ingested by Plaintiff were designed, tested, marketed, 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.

156. 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.

157. Defendants had a duty to comply with the applicable regulations. Notwithstanding this duty, Defendants breached this duty by designing, manufacturing, testing, labeling, distributing, marketing, advertising, and promoting the unapproved and unreasonably dangerous valsartan containing drugs to Plaintiff and Plaintiff's physicians.

158. 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.

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

160. 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.

161. 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.

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

163. 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.

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

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

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

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

WHEREFORE, Plaintiffs pray for judgment in Count IV against Defendants for damages for past, present and future.

COUNT V
FAILURE TO WARN

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

169. 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.

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

171. 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.

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

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

174. 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.

175. 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.

176. 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.

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

178. Plaintiff's physicians would not have prescribed, and Plaintiff would not have taken these valsartan-containing drugs had they known of the true safety risks related to their use.

179. 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.

WHEREFORE, Plaintiffs pray for judgment in Count V against Defendants for damages for past, present and future.

COUNT VI
LOSS OF CONSORTIUM

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

181. At all times material to this matter, Plaintiffs, Glenda Robertson and Wade Robertson were legally married.

182. As a direct and proximate result of Defendants' actions, Plaintiff Wade Robertson has suffered a loss of consortium, for which he is entitled to compensation.

WHEREFORE, Plaintiffs pray for judgment in Count VI against Defendants for damages for past, present and future.

COUNT VII
PUNITIVE DAMAGES

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

184. Upon information and belief, Defendants changed their valsartan-containing drug manufacturing processes in or about 2012, if not earlier.

185. According to the European Medicines Agency ("EMA") – which has similar jurisdiction to that of the FDA – "NDMA was an unexpected impurity believed to have formed as a side product after Defendants introduced changes to the manufacturing process in 2012."[55]

186. The world Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

187. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a "B2" rating, meaning that it is "probably carcinogenic to humans" with little or no human data.

188. Anecdotally, NDMA has also been used in intentional poisonings.[56]

189. Most assuredly, NDMA is not an FDA-approved ingredient for branded Diovan® or generic valsartan. None of Defendants' valsartan-containing drug products identifies NDMA as an ingredient on the products' labels or elsewhere.

190. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA contamination almost immediately.

191. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

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[55] *See* European Medicines Agency, UPDATE ON REVIEW OF RECALLED VALSARTAN MEDICINES, *at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail/003000.jsp&mid=WC0b01ac058004d5c1.

[56] *See* Quartz, A COMMON BLOOD-PRESSURE MEDICINE IS BEING RECALLED BECAUSE OF A TOXIC INGREDIENT, https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.
>
> 21 C.F.R. § 211.110(c).

And as reproduced above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

192. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the NDMA contamination in Defendants' valsartan-containing drug would have been discovered in 2012. Defendants were thus on (at minimum) constructive notice that their valsartan-containing drug were adulterated as early as 2012.

193. There are indications that Defendants had actual knowledge of valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

194. As alleged above, FDA investigators visited the manufacturing facilities in May 2017. In the words of FDA inspectors, Defendants "invalidat[ed] [OOS] results [without] scientific justification" and did not implement "appropriate controls … to ensure the integrity of analytical testing" and routinely disregarded sampling anomalies suggestive of impurities.

195. These discoveries by the FDA's investigators suggest that Defendants were specifically aware of impurities in the drugs being manufactured by Defendants, including specifically contamination of Defendants' valsartan-containing drug with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated valsartan into the U.S. market.

196. Defendants knowingly withheld or misrepresented information required to be submitted under the FDA's regulations, which information was material and relevant to the Plaintiffs' injuries.

197. Defendants were also specifically aware of the manufacturing issues at Defendants' facilities based on Defendants' awareness of cGMP violations as early as 2012 based on their own monitoring of Defendants and of the valsartan-containing drug being manufactured by Defendants and based on the FDA's inspections of Defendants' facilities in March 2007, May 2017, and July-August 2018.

198. Indeed, Defendant Solco and ZHP (as well as Huahai US) are owned by the same corporate parent, Huahai Pharmaceutical, and Solco was specifically aware, or should be imputed with actual knowledge, of ZHP's willful deviations from cGMPs. Solco and Huahai US have offices in the same office building in Cranbury, New Jersey.

199. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their valsartan-containing drug because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of the valsartan-containing drug only after the FDA had threatened an involuntary recall.

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

201. 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 an active ingredient, namely NDMA.

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

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

204. NDMA has been a known carcinogen for many years.

205. Further, Defendants failed to adequately test the product they were manufacturing, marketing, distributing, and selling to doctors and patients, like Plaintiff and Plaintiff's physicians. This inadequate testing went on for years, such that pills containing unreasonably dangerous and carcinogenic substances were distributed to millions, if not billions, of American consumers, as well as consumers throughout the world.

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

207. 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.

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

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

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

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

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

WHEREFORE, Plaintiffs pray for judgment in County VII against Defendants for punitive damages in an amount that will properly punish Defendants and deter others from like conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

(a) That process be issued as to Defendants Solco, Prinston, and Huahai;

(b) That Plaintiffs be granted a trial by jury;

(c) That Plaintiffs recover a judgment against the Defendants in an amount to be shown by the evidence at the trial of this case for the physical and mental pain and suffering, permanent disability, medical expenses, lost capacity to earn and labor, loss of consortium, and other necessary expenses, past, present and in the future incurred by them as a result of the Defendants' actions;

(d) Awarding punitive damages to the Plaintiffs;

(e) Awarding pre-judgment and post-judgment interest to the Plaintiffs;

(f) Awarding the costs and the expenses of this litigation to the Plaintiffs;

(g) Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and

(h) That the Court grant such other and further relief as it deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Date: June 5, 2019.

Respectfully submitted,

Javerbaum, Wurgaft, Hicks, Kahn, Wikstrom & Sinins, P.C

By: /s/ Roger W. Orlando
Roger W. Orlando, Esquire
13 Pine Street
Third Floor
Morristown, New Jersey 07960
Telephone: (973) 898-0404

CERTIFICATION PURSUANT TO R 4:5-1

The undersigned attorney for Plaintiffs certifies that the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration or administrative proceeding.

I certify that the foregoing statement made by me is true to the best of my knowledge, information and belief. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

DESIGNATION OF TRIAL COUNSEL

Pursuant to Rule 4:24-4, Plaintiffs designate Roger W. Orlando, Esquire as trial counsel in this matter.

Date: June 5, 2019

Respectfully submitted,

Javerbaum, Wurgaft, Hicks, Kahn, Wikstrom & Sinins, P.C

By: /s/ Roger W. Orlando

Roger W. Orlando,
Esquire 13 Pine Street
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Morristown, New Jersey
07960 Telephone: (973)898-0404

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-004228-19

Case Caption: ROBERTSON GLENDA VS SOLCO HEALTHCARE U.S ., LLC
Case Initiation Date: 06/05/2019
Attorney Name: ROGER W ORLANDO
Firm Name: ORLANDO FIRM, PC
Address: 13 PINE ST 3RD FL
MORRISTOWN NJ 07960
Phone:
Name of Party: PLAINTIFF : Robertson, Glenda, K
Name of Defendant's Primary Insurance Company (if known): None

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

06/05/2019
Dated

/s/ ROGER W ORLANDO
Signed