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UNITED STATES DISTRICT COURT FOR THE

EASTERN DISTRICT OF CALIFORNIA

Kevork Avedikian, an Individual,

Plaintiffs,

v.

Zhejiang Huahai Pharmaceutical Co., Ltd, Prinston Pharmaceutical, Inc. dba Solco Healthcare US, LLC, Solco Healthcare US, LLC, and Huahai U.S., Inc.

Defendants.

Case No. 1:19-at-121

COMPLAINT AND DEMAND FOR JURY TRIAL

JURY TRIAL DEMANDED

I. INTRODUCTION

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

II. PARTIES

I. PLAINTIFF

1. At all relevant times, Plaintiff Kevork Avedikian was and is a resident of the City of Fresno, County of Fresno, in the State of California.

II. DEFENDANTS

1. Active Pharmaceutical Manufacturers

i. Zhejiang Huahai Pharmaceutical Co., Ltd

2. 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.
3. Zhejiang Huahai Pharmaceutical Co., Ltd. is the parent company of subsidiaries Prinston Pharmaceutical Inc., Solco Healthcare, LLC, and Huahai U.S., Inc.
4. 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]

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

2. Drug Manufacturers

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

5. 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]

6. 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

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

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

3. Other Entities

ii. Huahai U.S., Inc.

9. 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.[5]

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

III. JURISDICTION AND VENUE

11. 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

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

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

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

13. 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 California, and they are all subject to personal jurisdiction in this District.

IV. PLAINTIFF'S MEDICATION

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

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

16. 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.

17. 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.

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

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

20. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012.[6]

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

I. NDMA

22. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.[7]

23. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[8]

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

25. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[9]

26. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[10] 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.[11]

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[6] https://www.forbes.com/sites/larryhusten/2012/09/25/another-one-bites-the-dust-diovan-patent-expires-but-generic-valsartan-is-mia/#4b43eaf92833.
[7] https://www.atsdr.cdc.gov/toxprofiles/tp141.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.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[11] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

27. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[12]

28. Exposure to high levels of NDMA has been linked to liver damage in humans.[13]

29. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[14]

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

31. 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.[15]

32. 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."[16]

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

II. NDEA.

33. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[17]

34. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[18]

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

36. 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.

37. Hematological effects were also reported in animal studies.[19]

38. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[20]

39. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[21]

40. 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."[22]

41. 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.[23]

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[17] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[18] 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.
[19] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[20] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[21] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[22] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[23] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.

III. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

42. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[24]

43. 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.[25]

44. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[26]

IV. RECALLS

45. 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.[27]

A. U.S. Recalls

46. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API)

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

supplied by Zhejiang Huahai Pharmaceuticals."[28] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[29]

47. 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."[30]

48. 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.[31]

49. 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."[32]

50. 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."

51. 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."[33]

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

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

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

levels of NDMA.[34] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[35]

54. 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**[36] (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.**

55. By way of comparison, NDMA is sometimes also found in water and foods, including meats, dairy products, and vegetables. The U.S. Health Department set strict limits on the amount of NDMA that is permitted in each category of food, but these limits are dwarfed by the amount of NDMA present in the samples of the valsartan-containing medications referenced above. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[37]

56. 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.[38]

57. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan (including those ingested by Plaintiff) and other ARB

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

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."[39]

4. Recalls in Other Countries

58. 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."[40]

59. 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.[41]

60. 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.[42]

V. THE FEDERAL REGULATORY LANDSCAPE

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

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

61. 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."[43]

62. 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.[44]

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

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

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

64. 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.[45]

65. 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.[46]

II. MISBRANDED AND ADULTERATED DRUGS

66. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[47]

67. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[48]

68. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[49]

69. A drug is adulterated:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[50]

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;"[51]

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

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. … No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label."[52]

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."[53]

70. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[54]

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."[55]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[56]

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, …"[57]

[52] 21 U.S.C. § 351(b).
[53] 21 U.S.C. § 351(d).
[54] 21 U.S.C. § 352(a)(1).
[55] 21 U.S.C. § 352(c).
[56] 21 U.S.C. § 352(e)(1)(A)(ii)
[57] 21 U.S.C. § 352(f).

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."[58]

f. "if it is an imitation of another drug;"[59]

g. "if it is offered for sale under the name of another drug."[60]

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."[61]

i. If the drug is advertised incorrectly in many manner;[62] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[63]

71. 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 PLAINTIFF WAS NOT VALSARTAN, BUT A NEW, UNAPPROVED, VALSARTAN-CONTAINING DRUG

72. 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.[64]

73. 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,

[58] 21 U.S.C. § 352(g).
[59] 21 U.S.C. § 352(i)(2).
[60] 21 U.S.C. § 352(i)(3).
[61] 21 U.S.C. § 352(j).
[62] 21 U.S.C. § 352(n).
[63] 21 U.S.C. § 352(p).
[64] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

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."[65]

74. 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.

75. 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.[66]

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).

76. 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.*

77. 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.

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

78. 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.

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

80. 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.[67] 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.

81. 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.

82. Because the valsartan-containing drugs ingested by Plaintiff were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

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

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

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

[68] 21 C.F.R. § 201.5.

[69] 21 C.F.R. § 801.15.

84. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[70] 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."[71]

86. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[72]

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

88. It is unlawful to introduce a misbranded drug into interstate commerce.[73] Thus, the valsartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

VI. ADHERENCE TO GOOD MANUFACTURING PRACTICES

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

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

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

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 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."

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.

VI. PLAINTIFF-SPECIFIC ALLEGATIONS

103. Between approximately October of 2015 and June 2018, Plaintiff Kevork Avedikian was prescribed and took generic valsartan to treat high blood pressure.

104. The valsartan ingested by 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.

105. On or around May 22, 2018, Plaintiff was diagnosed with Stomach Cancer.

106. As a result of Plaintiff's ingestion of contaminated valsartan, Plaintiff developed and was diagnosed with cancer, which caused permanent and disabling injuries.

I. CAUSATION

107. 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 and/or NDEA.

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

109. Plaintiffs 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 Plaintiffs or Plaintiff's physicians

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

110. Plaintiff and Plaintiff's 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. PLAINTIFFS' RESULTING DAMAGES AND INJURIES

111. Plaintiff suffered serious personal injuries as a direct and proximate result of the Defendants' failure to provide adequate warnings, failure to design, manufacture, sell, or distribute a safe product, and failure to adhere to safe manufacturing processes.

112. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiff suffered and will continue to suffer from severe injuries and damages, including but not limited to severe personal injuries, great emotional distress, and mental anguish.

113. 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. Plaintiff was injured and suffered injuries to Plaintiff's body and mind, the exact nature of which are not completely known to date;

b. Plaintiff sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages 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

114. Plaintiff had no reason until recently to suspect that Plaintiff's cancer was caused by Defendants' defective and unreasonably dangerous drug. Plaintiff did not know and could not have known through the exercise of reasonable diligence that the use of contaminated valsartan caused Plaintiff's injuries (or that 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.

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

116. 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.

117. 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 Plaintiff.

118. 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.

119. 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.

120. 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 Plaintiffs, Plaintiffs' physicians, and the public.

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

122. Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of Plaintiff and other patients.

VII. GENERAL ALLEGATIONS

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

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

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

126. 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.

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

I. REPRESENTATIONS

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

129. Defendants misrepresented, downplayed, and/or omitted the safety risks of the valsartan-containing drugs ingested by Plaintiff to physicians and patients, including Plaintiff and Plaintiff's physicians by failing to disclose the presence of NDMA and/or NDEA in their products and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

130. 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.

131. 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.

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

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

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

135. 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.

136. 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.

137. 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.

138. 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.

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

VIII. CLAIMS FOR RELIEF

I. STRICT LIABILTY- MANUFACTURING DEFECT

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

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

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

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

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

145. 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."[74]

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

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

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

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

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

II. STRICT LIABILITY- FAILURE TO WARN

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

151. 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.

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

153. 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.

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

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

156. 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.

157. 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.

158. 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.

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

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

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

III. STRICT LIABILITY- DESIGN DEFECT

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

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

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

165. 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.

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

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

168. 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.

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

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

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

IV. NEGLIGENCE

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

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

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

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

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

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

V. NEGLIGENCE PER SE

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

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

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

181. 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.

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

183. 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.

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

185. 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.

186. 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.

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

188. 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.

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

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

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

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

VI. BREACH OF EXPRESS WARRANTY

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

194. Defendants utilized false and deceptive product labels and other labeling, as well as advertising to promote, encourage, and urge the use, purchase, and utilization of these drugs by representing the quality and safety to health care professionals, Plaintiff, and the public in such a way as to induce their purchase or use.

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

196. 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.

197. 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.

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

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

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

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

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

VII. BREACH OF IMPLIED WARRANTY

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

204. 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.

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

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

207. Defendants breached their implied warranty to Plaintiff in that Defendants' products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of state common law principles.

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

VIII. FRAUD

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

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

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

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

213. 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.

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

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

216. Plaintiffs and/or Plaintiff's physicians would not have decided to prescribe and ingest these drugs had they known of the true safety risks related to such use, all of which were known to Defendants.

217. 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.

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

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

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

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

IX. NEGLIGENT MISREPRESENTATION

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

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

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

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

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

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

228. 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.

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

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

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

PRAYER FOR RELIEF

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

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

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

C. For specific damages according to proof;

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

E. For Restitution and disgorgement of profits;

F. For Punitive and Exemplary damages according to proof;

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

H. For reasonable attorneys' fees;

I. the costs of these proceedings; and

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

Dated: February 12, 2019

Respectfully Submitted,

/s/

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Attorneys for Plaintiff

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Kevork Avedikian, an Individual

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Behram Parekh
KIRTLAND & PACKARD LLP
1638 S. Pacific Coast Hwy, Redondo Beach, CA 90277

DEFENDANTS

Zhejiang Huahai Pharmaceutical Co., Ltd, Mylan Laboratories, Ltd., Prinston Pharmaceutical, Inc. dba Solco Healthcare US, LLC, Solco Healthcare US, LLC, Huahai U.S., Inc.

County of Residence of First Listed Defendant Middlesex
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Unknown

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

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

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

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

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C 1332

Brief description of cause:
Product liability case stemming from Plaintiff ingesting a carcinogenic pharmaceutical drug

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE JPML Petition Pending DOCKET NUMBER MDL No. 2875

DATE
02/12/2019

SIGNATURE OF ATTORNEY OF RECORD
/s/ Behram V. Parekh

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.