UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION

JEFFREY A. BERRYMAN, and
CHITIQUA HOCKER,
Plaintiffs,

v.

CAMBER PHARMACEUTICALS, INC.,

Serve: The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

and

HETERO USA, INC.,

Serve: W/K Inc. Services, Inc.
3500 South Dupont Hwy.
Dover, DE 19901

and

THE KROGER COMPANY,

Serve: Corporation Service Company
421 W. Main Street
Frankfort, KY 40601

Defendants.

Case No.:

COMPLAINT AND JURY DEMAND

COMPLAINT

Plaintiffs, Jeffrey A. Berryman and Chitiqua Hocker ("Plaintiffs"), by counsel, hereby bring this Complaint for damages against Defendants, Camber Pharmaceuticals, Inc., Hetero USA, Inc., and The Kroger Company ("Defendants"), and allege the following:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiffs as a direct and proximate result of ingesting prescription Valsartan drugs designed, manufactured, marketed, produced, packaged, advertised, distributed, and sold by Defendants, which was adulterated, misbranded, unapproved, and contaminated with known carcinogenic substances, specifically N-nitrosodimethylamine ("NDMA") and N-Nitrosodiethylamine ("NDEA").

PARTIES

2. Plaintiff, Jeffrey A. Berryman, is and at all relevant times was a resident of Lexington, Fayette County, in the Commonwealth of Kentucky. Plaintiff brings this action for personal injuries sustained by exposure to adulterated, misbranded, unapproved, and contaminated Valsartan drugs designed, manufactured, marketed, produced, packaged, advertised, distributed, and sold by Defendants.

3. Plaintiff, Chitiqua Hocker, is and at all relevant times was a resident and citizen of Lexington, Fayette County, in the Commonwealth of Kentucky. Plaintiff, Chitiqua Hocker, is the spouse of Plaintiff, Jeffrey A. Berryman, and brings a claim for loss of consortium.

4. Defendant, Camber Pharmaceuticals, Inc. ("Defendant" or "Camber"), is and at all relevant times was, a Delaware corporation, with its principal place of business located at 1031 Centennial Avenue, Piscataway, New Jersey 08854. Defendant Camber is and has been engaged in the design, manufacturing, sale, marketing, and distribution of Valsartan products, including generic valsartan products, that were adulterated, misbranded, unapproved and contaminated with known carcinogens, including NDMA and NDEA. Defendant Camber's website states that Hetero Drugs Limited, based in India, is the parent company of Defendant Camber.

5. Defendant, Hetero USA, Inc. ("Defendant" or "Hetero"), is and at all relevant times was, a Delaware corporation, with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero is the U.S. branch office of Hetero Drugs Limited, the parent company of Defendant Camber. Defendant Hetero acts as the agent and alter ego of Hetero Drugs Limited in the United States. Hetero designs, manufactures, markets, produces, packages, distributes, and sells valsartan-containing drugs.

6. Defendant, The Kroger Company ("Defendant" or "Kroger"), is and at all relevant times was a Delaware corporation, with its principal place of business located at 1014 Vine Street, Cincinnati, Ohio. Kroger is authorized to do business in the Commonwealth of Kentucky and is doing business in the Commonwealth of Kentucky. Defendant Kroger should be served at its registered agent for service of process, Corporation Service Company, 421 West Main Street, Frankfort, Kentucky 40601. Defendant Kroger markets, advertises, distributes, and sells Valsartan and valsartan-containing drugs, including the adulterated, misbranded, unapproved and contaminated Valsartan ingested by Plaintiff Jeffrey A. Berryman.

7. Defendants transacted and conducted business in the Commonwealth of Kentucky that relates to the allegations in this Complaint.

8. Defendants derived substantial revenue from goods and products sold and used in the Commonwealth of Kentucky.

9. Defendants expected or should have expected their acts to have consequences within the Commonwealth of Kentucky, and derived substantial revenue from interstate commerce.

10. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting business and activities within the Commonwealth of Kentucky, thus invoking the benefits and protections of its laws.

11. Upon information and belief, Defendants designed, manufactured, marketed, produced, packaged, advertised, distributed, and sold Valsartan and valsartan-containing drugs that were adulterated, misbranded, unapproved and contaminated with known carcinogens, including NDMA and NDEA.

JURISDICTION AND VENUE

12. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants. Defendants are incorporated and/or have their principal places of business outside of the state in which Plaintiffs reside.

13. The amount in controversy between Plaintiffs and Defendants exceeds $75,000, exclusive of interest and costs.

14. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

15. Venue is proper within this district pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this district. Furthermore, Defendants sold, marketed, advertised, and distributed Valsartan and valsartan-containing drugs within the Eastern District of Kentucky that were adulterated, misbranded, unapproved and contaminated with known carcinogens, including NDMA and NDEA. Also, a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL ALLEGATIONS

16. The prescription medication that is the subject of this action is a drug that

Defendants designed, manufactured, marketed, produced, packaged, advertised, distributed, and sold under the name "Valsartan."

17. Valsartan was originally marketed, distributed, and sold under the brand name, Diovan. Valsartan is a prescription medication used for the treatment of high blood pressure and heart failure.

18. 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 easier, thereby lowering blood pressure. The drug binds to angiotensin type II receptors (ATI) working as an antagonist. Valsartan can be sold by itself or as a single pill which combines valsartan with amlodipine or HCTZ (or both).

19. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012. Shortly thereafter, the FDA began to approve generic versions of Valsartan and valsartan-containing drugs (those pills combining valsartan with amlodipine or HCTZ, or both), including those manufactured by Hetero and Camber.

20. Defendants, Hetero and Camber, began manufacturing Valsartan and valsartan-containing drugs (hereinafter, "Valsartan"). The process used by Defendants to manufacture Valsartan ultimately produced Valsartan that was contaminated with known carcinogens, including NDMA and NDEA.

NDMA

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

22. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile

chemical that forms in both industrial and nature processes."[1]

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

24. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[2]

25. The U.S. Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[3] 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.[4]

26. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[5]

27. Exposure to high levels of NDMA has been linked to liver damage in humans.[6]

28. 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." [7]

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

30. On July 27, 2018, the FDA published a press release, explaining the reason for its

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

concern regarding the presence of NDMA found in valsartan-containing drugs. In pertinent part:

> NDMA has been found to increase the occurrence of cancer in animal studies… Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.
> …
> The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.[8]

31. 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]

NDEA

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

33. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[10]

34. NDEA is an even more potent carcinogen than NDMA, and according to the Environmental Protection Agency, even short-term exposure to NDEA can cause liver and other types of tumors, including the kidneys. Similarly, hematological effects were also reported in animal studies.[11] Tests conducted on rats, mice, and hamsters demonstrated NDEA via oral exposure results in high to extreme toxicity.[12]

35. The New Jersey Department of Health advises that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[13] The New Jersey

[8] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

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

[10] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-valsartan-products-and-reports-finding-additional

[11] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf

[12] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf

[13] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).

Department of Health further 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."[14]

36. 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.[15]

RECALLS OF CONTAMINATED VALSARTAN

37. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[16]

38. Solvents used to produce tetrazole ring, such as N-Dimethyformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of chemical reactions.[17] The pharmaceutical industry has long been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[18]

39. Defendants Camber and Hetero designed, manufactured, produced, packaged, marketed, distributed, and sold Valsartan contaminated with NDMA and NDEA. Defendant Kroger marketed, packaged, advertised, distributed and sold this contaminated and dangerous Valsartan to patients nationwide.

40. Upon information and belief, the presence of NDMA and NDEA in the contaminated Valsartan resulted from a manufacturing process change that took place in or around 2012.[19]

41. On July 13, 2018, the FDA announced a recall of certain batches of Valsartan after

[14] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf
[15] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf
[16] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001
[17] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001
[18] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf
[19] https://www.fda.gov/media/116520/download

discovering the presence of NDMA in certain batches of Valsartan. The FDA published a list of suppliers, distributors and manufacturers that distributed and sold contaminated Valsartan, noting the drugs subject to the recall do "not meet our safety standards."[20] The FDA further stated that the FDA was working with affected companies to reduce or eliminate the Valsartan active pharmaceutical ingredient ("API") impurity from future products, and identified Valsartan API from Zhejiang Huahai Pharmaceuticals Co., Ltd., as a manufacturer with Valsartan subject to the recall.[21] The initial recall was limited to "all lots of non-expired products that contain the ingredient Valsartan supplied by the [API] supplied by this specific company."

42. Just five (5) days later, the FDA published another press release concerning the recall, conveying the FDA's determination that, "the recalled valsartan products pose an unnecessary risk to patients."[22] The FDA additionally determined that, "[s]ome levels of the impurity may have been in the valsartan-containing products for as long as four years."[23]

43. After the initial recall in July 2018, the list of Valsartan subject to recall for NDMA contamination continued to grow.

44. On August 9, 2018, the FDA announced that it was expanding the recall to include Valsartan manufactured by other API manufacturers, including Hetero, labeled as Camber Pharmaceuticals, Inc., noting these recalled pills also contained unacceptable levels of NDMA.[24] The August 9, 2018 press release stated: "Test results from Hetero Labs show the amount of NDMA found in its valsartan API exceeds acceptable levels…"[25]

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[20] https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity

[21] Id.

[22] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

[23] Id.

[24] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

[25] Id.

45. Camber's website notes it commitment to quality, stating that Camber "provide[s] the highest quality generics for our patients and our customers." The website further states that "[b]oth our American and Indian based manufacturing facilities utilize a quality and compliance process that meets extensive governmental regulations by the US Food and Drug Administration." Camber further warrants on its website that its generic drugs are "copies of the brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use." As described herein, however, these representations are false as its Valsartan medications were contaminated with carcinogenic NDMA.

46. This is not the first time that Camber and Hetero's manufacturing processes have been questioned by the FDA. A previous investigation in 2016 by the FDA revealed significant violations of current good manufacturing processes for finished pharmaceuticals. This resulted in a warning letter from the FDA in August of 2017. This latest incident is yet another unfortunate data point exemplifying a pattern and practice of deficient, careless, and negligent manufacturing and distribution practices of Camber and Hetero.

47. On October 5, 2018, the FDA posted the results of testing conducted on samples of recalled Valsartan. The results noted 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** (emphasis added).[26] 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 level determined to be "reasonably safe for human ingestion."

[26] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

48. By way of comparison, NDMA is sometimes found in water and foods, including meats, dairy products, and vegetables. The U.S. Health Department sets strict limits on the amount of NDMA that is permitted in each category of food, but these limits are entirely dwarfed by the amount of NDMA present in the samples of Valsartan medications referenced herein. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[27]

49. On November 21, 2018, the FDA announced a new recall, this time because NDEA was detected in Valsartan. Additional recalls of Valsartan found to contain NDEA followed thereafter. The notices stated the recalls related to unexpired Valsartan products.[28]

50. 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 drugs that he FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, the 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 an impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."[29]

A. Recalls In Other Countries.

51. The European Medicines Agency (EMA) recalled many batches of Valsartan. According the EMA, "[t]he review of the 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."[30]

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[27] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

[28] Id.

[29] Id.

[30] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group

52. In light of the EMA's findings, Zhejiang Huahai Pharmaceutical Co., Ltd., along with another API manufacturer Zheijan Tianyu, are not presently authorized to produce Valsartan for medications distributed in the European Union.[31]

53. Health Canada also issued a recall of Valsartan medications on July 9, 2018, noting the presence of NDMA as the reason. Health Canada similarly stated that NDMA is a potential human carcinogen.[32]

FRAUDULENT CONCEALMENT AND EQUITABLE TOLLING OF THE STATUTE OF LIMITATIONS

54. Defendants knowingly and intentionally kept Plaintiffs, their physicians, and the medical community in the dark as to the information necessary to the pursuit of claims, until such time as the information was publicly disseminated in late 2018. Plaintiff and his physicians did not have the means to test for possible contamination, nor information to indicate testing was necessary, with respect to the Valsartan manufactured and distributed by Defendants. Thus, Plaintiffs could not have reasonably discovered their claims before public dissemination of the information concerning the contamination of the Valsartan.

55. Defendants were obligated to disclose facts relating to possible contamination that were in their exclusive possession as they obtained this information. The failure to do so constitutes intentional conduct committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs. The information concerning contamination was purposefully withheld, was material, and was information that consumers such as Plaintiffs could not have learned without Defendants' disclosure.

[31] https://www.ema.europa.eu/en/news/update-review-valsartan-medicines-risk-ndma-remains-low-related-substance-ndea-also-being

[32] http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem

56. At a minimum, Defendants withheld the information concerning the contaminated Valsartan that it continued to manufacture, market and distribute to consumers, until the formal recall of Defendants' Valsartan API in August 2018. Accordingly, consumers, such as Plaintiffs, were misled into believing that they did not receive contaminated Valsartan, or that they had no recourse.

57. As a result of Defendants' actions and failure to disclose despite the duty to disclose, Plaintiffs were unaware, and could not reasonably know or have learned through reasonable diligence that the Valsartan Plaintiff ingested was contaminated and that the contaminated Valsartan exposed Plaintiff to the risks and injuries alleged herein and that those risks and injuries were the direct and proximate result of Defendants' acts and omissions.

58. Any applicable statute of limitations has been tolled and Defendants are estopped from relying on such limitations periods as a defense, by the knowing and active concealment of material facts known by Defendants, where Defendants had a duty to disclose those facts as they obtained them, but failed to do so. In addition, Defendants are estopped from relying on any statute of limitations because of Defendants' internal concealment of material facts.

59. Because of Defendants' fraudulent concealment of material facts, upon which Plaintiffs relied, Plaintiffs are well within the statute of limitations at the time of this filing.

FEDERAL REGULATORY LANDSCAPE

60. 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. Generic drugs must be the bioequivalent according to these standards, meaning 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."[33]

61. While brand-name drugs undergo a more rigorous review before initial market approval, generic manufacturers are permitted to submit an abbreviated new drug application (ANDA) which only requires a generic manufacturer to demonstrate the generic medicine is the same as the brand in the following ways:

a. The active ingredient is the same;

b. The generic has the same strength, use indications, form (tablet, injectable, etc.) and route of administration (oral, topical, etc.);

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

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

e. The container in which the generic will be shipped and sold is appropriate and the label is identical as the brand's label.[34]

62. The Valsartan ingested by Plaintiff was approved by the FDA, based on Defendants' representations in its ANDA, that Defendants' Valsartan met the applicable criteria.

63. ANDA applications do not require drug manufacturers to repeat animal or clinical studies or other research on ingredients or dosage forms that have already, previously, been approved for safety and effectiveness.[35]

64. Because generic drugs are supposed to be virtually identical to their brand counterparts, they must also have the same risk and benefits of the brand.[36]

[33] https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q2
[34] https://www.fda.gov/drugs/generic-drugs/generic-drug-facts
[35] Id.
[36] Id.

MISBRANDED AND ADULTERATED VALSARTAN

65. The manufacture of any misbranded or adulterated drug is prohibited under federal law. 21 USC § 331(g).

66. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited. 21 USC § 331(a).

67. The receipt in interstate commerce of any adulterated or misbranded drug is likewise unlawful. 21 USC § 331(c).

68. 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." 21 USC § 351(a)(2)(A).

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." 21 USC § 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 therefore set forth in such compendium if its difference in strength, quality or purity from such standard is plainly stated

on its label." 21 USC § 351(b).

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 therefore." 21 USC § 351(d).

69. A drug is misbranded:

a. "If its labeling is false or misleading in any particular." 21 USC § 352(a)(1).

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." 21 USC § 352(c).

c. If the labeling does not contain, among other things, "the proportion of each active ingredient." 21 USC § 352(e)(1)(A)(ii).

d. "Unless its labeling bears (1) adequate directions for use; (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." 21 USC § 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." 21 USC § 352(g).

f. "If it is an imitation of another drug." 21 USC § 352(i)(2).

g. "If it is offered for sale under the name of another drug." 21 USC § 352(i)(3).

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." 21 USC § 352(j).

i. If the drug is advertised incorrectly in any manner. 21 USC § 352(n).

j. If the drug's "packaging or labeling is in violation of an applicable regulation…" 21 USC § 352(p).

70. As set forth in this Complaint, Defendants' drug was misbranded and adulterated pursuant to applicable law, specifically in violation of the regulations cited above.

71. Alternatively, the drug ingested by Plaintiff was not misbranded and adulterated Valsartan, but rather, a new, unapproved, valsartan-containing drug, that the FDA had never reviewed or assessed for safety because it was improperly and illegally sold before approval of safety or effectiveness by the FDA.

a. When a generic drug manufacturer ceases to manufacture a drug that meets all terms of its approval, and ceases to manufacture a drug that is the same as its corresponding brand counterpart, the manufacturer has thereby created an entirely new (yet unapproved) drug. Any new, unapproved drug cannot be required to have the same label as a brand name drug because the two products are not the same. By creating a new, unapproved drug, rather than a generic bioequivalent of the brand drug, the manufacturer forfeits the shield of federal preemption.[37]

72. 21 CFR 210.3(b)(7) defines an "active ingredient" in drugs 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

[37] See generally, Pliva v. Mensing, 564 U.S. 604 (2011).

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."

73. NDMA and NDEA both have the ability to cause cancer by triggering genetic mutation in humans and this mutation affects the structure of the human body such that NDMA and NDEA are by definition, active ingredients in the drug ingested by Plaintiff.

74. The FDA further requires that whenever a new active ingredient is added to a drug, the drug is thereby an entirely new drug, for which the manufacturer must submit a New Drug Application to the FDA for approval. Absent such an application, followed by review and presumably approval by the FDA, the new drug remains a distinct, yet unapproved product. 21 CFR 310.3(h).

75. At the very least, drugs with different and dangerous ingredients than their corresponding brand counterparts are considered adulterated and misbranded under federal law, the sale of which and introduction into interstate commerce is illegal pursuant to the Food, Drug and Cosmetic Act (FDCA). 21 USC § 331.

LABELING AND MANUFACTURING PRACTICES

76. A manufacturer is required to give adequate directions for the use of any pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[38] and conform to the requirements governing the appearance of the label.[39]

77. Labeling encompasses all written, printed or graphic material accompanying the drug or device,[40] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" and patient education monographs, but also advertising. If a

[38] 221 CFR 201.5
[39] 21 CFR 801.15
[40] Id., 65 Fed. Reg. 14286 (2000).

manufacturer labels a drug, but omits ingredients, that drug is misbranded under the law.[41]

78. "Most if not all labeling is advertising. The term 'labeling' is defined by 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."[42]

79. The NDMA and/or NDEA in Defendants' drugs that were ingested by Plaintiff, but were not disclosed by Defendants as ingredients renders the drugs ingested by Plaintiff misbranded and adulterated. It is unlawful to introduce a misbranded drug into interstate commerce.[43] Thus, the drugs that Plaintiff ingested were not only misbranded and adulterated, but were illegally distributed and sold.

80. In designing, manufacturing, marketing, producing, packaging, advertising, distributing and selling contaminated, misbranded and adulterated drugs ingested by Plaintiff, Defendants violated the following Current Good Manufacturing Practices (CGMP) under 21 CFR 200, *et seq.*:

a. 21 CFR 201.6 states "the 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.

b. 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 with other substances, must be listed. The failure to identify the presence of a

[41] 21 CFR 201.6; 201.10.
[42] US v. Research Labs, 126 F.2d 42, 45 (9th Cir. 1942).
[43] 21 USC § 331(a).

material ingredient renders the drug misbranded.

c. Section 201.56 provides requirements for drug labeling, including:

   i. The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

   ii. The labeling must be accurate and must not be misleading.

   iii. The labeling must be based upon human data, and no claims can be made if there is insufficient evidence of effectiveness.

d. Section 202.1 requires that the ingredients of the drug appear in advertisements, which must also contain true statements of information relating to side effects.

e. 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 it purports or is represented to possess. 21 CFR 210.1(a). Failure to comply with any of these regulations renders a drug adulterated. 21 CFR 210.1(b).

f. Section 210.3(7) defines an active ingredient, which includes any 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 a specified activity or effect.

g. Section 211 covers the buildings and facilities for pharmaceutical manufacturers and includes strict regulations as to condition, lighting, ventilation, temperature, and personnel training. Specifically, Sections

211.100-211.115 require manufacturers to have written procedures for production and process control to ensure consistency and quality. Section 211.160 requires 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.

h. Sections 211.165, 211.166 and 211.170 require appropriate sampling and stability testing be done and further, that "an appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient" be retained.

i. Section 211, subpart J, requires product production and control records to be reviewed by a quality control unit to determine compliance, accompanied by a written record of investigation, as well as all control records, including those for packaging and labeling, to be reviewed and approved by a quality control unit before any batch is released or distributed. "Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed." 211.192. Subsection J likewise requires written records of maintenance, laboratory records, distribution records, and complaint files.

PLAINTIFF-SPECIFIC ALLEGATIONS

81. Between approximately 2013 and May 2019, Plaintiff Jeffrey A. Berryman was prescribed and ingested Valsartan to treat high blood pressure and heart failure.

82. The Valsartan ingested by Plaintiff was manufactured and sold by the above-

captioned Defendants and was subject to the recall first issued by the FDA in August 2018.

83. On or about September 22, 2017, Plaintiff Jeffrey A. Berryman was diagnosed with both lung and pancreatic cancer. The development of Plaintiff's cancers was proximately and actually caused by his ingestion of contaminated Valsartan.

84. As a result of his injury, Plaintiff has suffered significant bodily injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity and have and will incur past and future medical expenses.

85. Upon information and belief, Plaintiff's prescribing physicians would not have prescribed Valsartan to Plaintiff and would have changed the way in which they treated Plaintiff's relevant conditions, but for Defendants' concealment of the true risks associated with its contaminated Valartan.

86. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish and deter similar conduct in the future.

CAUSES OF ACTION

I. STRICT LIABILITY – MANUFACTURING DEFECT

87. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

88. At all times herein mentioned, Defendants, designed, tested, manufactured, marketed, produced, packaged, advertised, distributed, and sold Valsartan, placing it into the stream of commerce, including the Valsartan ingested by Plaintiff.

89. The drug ingested by Plaintiff was expected and did reach Plaintiff without

alterations or substantial change in its condition as designed, tested, manufactured, produced, packaged, distributed, and sold by Defendants.

90. At all relevant times, the drugs ingested by Plaintiff contained manufacturing defects in that they differed from the brand equivalent, thereby rendering the product defective and unreasonably dangerous to patients, such as Plaintiff. Defendants' Valsartan was expected and reached Plaintiff in the same defective and unreasonably dangerous condition.

91. Defendants were required to manufacture Valsartan that conformed to the approved specifications and that was the bioequivalent to the brand counterpart, Diovan, which did not contain NDMA nor NDEA. The Valsartan manufactured by Defendants 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."[44]

92. Defendants failed to meet these requirements by utilizing a flawed and unlawful manufacturing process that resulted in contaminated Valsartan that was defective and dangerous to patients such as Plaintiff.

93. Instead of following the applicable requirements, Defendants manufactured a valsartan-containing drug that was defective, dangerous, and contained harmful active ingredients, including known carcinogens.

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

95. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

[44] https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers

96. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

97. By reason of the foregoing, the Defendants have become strictly liable in tort to Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product.

98. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

II. STRICT LIABILITY – FAILURE TO WARN

99. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

100. At all relevant times, Valsartan was designed, tested, manufactured, marketed, produced, packaged, advertised, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

101. Plaintiff was administered and ingested Valsartan for its intended purpose and used Valsartan in the foreseeable manner normally intended, recommended, promoted, advertised, and marketed by Defendants.

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

control.

103. Specifically, Defendants should have warned Plaintiff and his physicians about the risks of ingesting levels of NDMA and/or NDEA that exceed thresholds deemed to be safe.

104. As described herein, Defendants had a duty to be aware of and knew or should have known of many or all such risks associated with Defendants' Valsartan, but failed to disclose these risks and/or misrepresented the risks.

105. Defendants knew or should have known that ingesting carcinogenic substances such as NDMA and NDEA can cause cancer and Defendants breached their duty to physicians and patients, such as Plaintiff, by failing to warn of the specific risks of Defendants' Valsartan, including its contamination with known carcinogens.

106. Defendants knew that physicians would prescribe their Valsartan to patients, such as Plaintiff, based upon the information Defendants provided, including information regarding the safety and efficacy of the drugs.

107. Plaintiffs did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiffs.

108. Plaintiffs could not have discovered any defect in the Valsartan Plaintiff ingested through the exercise of reasonable care.

109. Defendants, as manufacturers and distributors, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of injuries associated with Valsartan was incomplete and inadequate.

110. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the use of their Valsartan drugs, including those that are part

of the recall, which were ingested by Plaintiff.

111. Further, Defendants marketed, distributed and sold an unapproved, misbranded, and adulterated drug without an adequate and approved warning label. Plaintiff's physicians would not have prescribed and Plaintiff would not have ingested a defective, dangerous, contaminated, and unapproved drug, had they known the true risks associated with it.

112. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

113. By reason of the foregoing, the Defendants have become strictly liable in tort to Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product.

114. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

III. STRICT LIABILITY – DESIGN DEFECT

115. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

116. At all times herein mentioned, Defendants, designed, tested, manufactured, marketed, produced, packaged, advertised, distributed and sold Valsartan, placing it into the stream of commerce, including the Valsartan ingested by Plaintiff.

117. The drug ingested by Plaintiff was expected and did reach Plaintiff without

alterations or substantial change in its condition as designed, tested, manufactured, produced, packaged, distributed, and sold by Defendants.

118. For the reasons described herein, the Valsartan ingested by Plaintiff was adulterated and unreasonably dangerous as it contained known carcinogenic active ingredients, including NDMA and/or NDEA.

119. Defendants' Valsartan was defectively designed because it was unsafe and unreasonably dangerous for the purposes intended by Defendants (to treat high blood pressure and/or heart failure) in the manner promoted and advertised by Defendants.

120. Defendants' Valsartan was defective and unreasonably dangerous in its design, construction and composition, and due to inadequate testing and quality control.

121. Plaintiff ingested the Defendants' Valsartan as reasonably foreseeable and in the manner intended, recommended, promoted, and marketed by Defendants, but the drugs failed to perform safely and as an ordinary consumer would expect. The risks of the drugs outweighed any benefit when used for the purpose and as intended and foreseeable by Defendants.

122. Defendants' Valsartan was designed in a way that caused users to suffer injuries including, but not limited to cancer.

123. These foreseeable risks of harm associated with known carcinogens could have been reduced or avoided by adopting a reasonable alternative design, as originally approved by the FDA, and adequate testing to ensure bioequivalence with the brand counterpart. However Defendants did not adopt a design that would ensure these drugs were reasonably safe, nor an adequate testing and quality control system to ensure safety.

124. Plaintiff ingested and Plaintiff's physicians prescribed Defendants' Valsartan in the manner intended and reasonably foreseeable by Defendants, and were not aware of any of the

aforementioned defects at any time prior to the injuries caused by Defendants' Valsartan.

125. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

126. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

127. By reason of the foregoing, the Defendants have become strictly liable in tort to Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product.

128. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

IV. NEGLIGENCE

129. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

130. Defendants marketed, advertised, packaged, and sold these drugs for the benefit of Plaintiff.

131. Defendants owed Plaintiff and his physicians a duty to exercise reasonable care under the circumstances, particularly in light of the prevailing scientific knowledge at the time the products were manufactured, distributed, and sold.

132. At all relevant times, Defendants owed Plaintiff a duty to exercise reasonable care in the design, manufacture, testing, marketing, production, advertising, distribution, selling, and post-market safety monitoring of Defendants' Valsartan, including a duty to ensure that the products did not cause users such as Plaintiff to suffer unreasonable, dangerous side effects when used in the foreseeable and intended manner.

133. As described in this Complaint and through Defendants' actions, misrepresentations, omissions and failures to act, Defendants breached their duties to Plaintiffs and Plaintiffs' physicians, including by failing to perform adequate testing, and quality control of their products, failing to use due care in the preparation, design, development and manufacture of Valsartan, and failing to adequately warn about contaminated Valsartan.

134. 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 wellbeing.

135. Defendants, individually and collectively, had a duty to adequately test, control the quality of their products, and use due care in the preparation, design, development and manufacture of their products but failed to do so.

136. Defendants negligently and recklessly represented to Plaintiffs, physicians, and the medical community, who Defendants knew relied upon their representations, that their Valsartan was safe for use and distribution, and that the utility of their Valsartan outweighed any risk in use for intended purposes.

137. Defendants omitted, suppressed, and/or concealed material facts concerning their Valsartan, including its contamination with known carcinogens, including NDMA and NDEA. Further, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or

otherwise understated the serious nature of the contamination and risks associated with their drugs because of the contamination.

138. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

139. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

140. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

V. GROSS NEGLIGENCE

141. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

142. Defendants owed a duty of care to Plaintiffs to manufacture, produce, market, distribute, and sell the subject Valsartan free from harmful and dangerous defects and impurities.

143. Defendants breached this duty by manufacturing, producing, marketing, distributing, and selling Valsartan that was indisputably contaminated with known carcinogens, NDMA and NDEA.

144. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

145. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

146. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

VI. BREACH OF EXPRESS WARRANTY

147. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

148. The aforementioned designing, manufacturing, testing, producing, packaging, analyzing, merchandizing, advertising, promoting, supplying, distributing, and selling of Valsartan was expressly warranted to be safe for use by Plaintiffs. Defendants represented that their Valsartan was safe, effective, fit for use as intended, to treat elevated blood pressure and heart failure, of merchantable quality, adequately tested, and that it was the bioequivalent of its brand counterpart.

149. Defendants utilized false and deceptive product labels and other labeling, as well as advertising to promote, encourage, and urge the use, purchase, and sale of Defendants' Valsartan drugs by representing the quality and safety in the medical community and to Plaintiff, in such a way as to induce their use and purchase. Through these representations, Defendants made express warranties that their Valsartan drugs would conform to the representations.

150. Defendants represented and warranted that their Valsartan was safe and effective

when used by individuals such as Plaintiff, in the manner intended and foreseen by Defendants. Defendants represented the Valsartan they manufactured, packaged and distributed was the "generic" Diovan as approved by the FDA, and that their Valsartan only contained ingredients as disclosed on the labeling.

151. Defendants' representations, as described herein, constitute affirmations of fact or promises made related to the Valsartan and created an express warranty that the goods conformed to the affirmations of fact and promises. Defendants' Valsartan did not conform to the express representations and warranties Defendants made, and was not the generic Diovan approved by the FDA.

152. At all relevant times, Defendants' Valsartan was contaminated with known carcinogens, specifically NDMA and NDEA, and did not perform in accordance with the Defendants' representations because Diovan did not contain NDMA nor NDEA, and because Defendants' Valsartan is not safe and can cause cancer.

153. At all relevant times, Defendants' Valsartan did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

154. In deciding to purchase and ingest Defendants' Valsartan, Plaintiff, his physicians, and the medical community relied upon Defendants' express warranties.

155. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

156. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses,

lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

157. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

VII. BREACH OF IMPLIED WARRANTY

158. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

159. Defendants' Valsartan drugs were not reasonably fit for the ordinary purpose 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.

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

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

162. Plaintiffs and Plaintiffs' healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants, and upon the Defendants' implied warranty that Defendants' Valsartan was safe, of merchantable quality, and fit for use.

163. Defendants breached their implied warranties to Plaintiff int hat Defendants' Valsartan was not of merchantable quality, safe and fit for its intended use, or adequately tested.

164. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

165. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

166. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

VIII. FRAUD

167. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

168. Defendants had a confidential and special relationship with Plaintiff and/or Plaintiffs' physicians because of Defendants' superior knowledge as to their dangerous and irresponsible practices of improperly promoting unapproved, dangerous, unsafe and contaminated drugs containing known carcinogens.

169. Upon information and belief, Defendants were aware that the Valsartan API they designed, manufactured, produced, packaged, distributed and sold to consumers such as Plaintiff, contained dangerous carcinogenic compounds, specifically NDMA and NDEA.

170. Defendants had an affirmative duty to fully and adequately control the quality of their drugs, adequately test for same, and adequately warn the public, including Plaintiff, of the true health and safety risks associated with Defendants' Valsartan, specifically, that Defendants' Valsartan contained unsafe levels of NDMA and/or NDEA.

171. Defendants also had a duty to disclose their dangerous and irresponsible practices

of improperly designing, testing, manufacturing, marketing, selling, an distributing drugs that did not have FDA approval as indicated, were not the bioequivalent of the brand counterpart as indicated by Defendants' labeling, and which had not been reviewed, analyzed, or studied by the Defendants or any regulatory body.

172. Defendants also had a duty not to conceal risks associated with their Valsartan.

173. Defendants fraudulently and intentionally misrepresented and/or fraudulently concealed material and important health and safety product risk information as described herein.

174. Defendants knew and intended to cause Plaintiff and Plaintiff's physicians to rely on their concealment of information and/or misrepresentations about the safety risks related to their drugs and to induce them to utilize their drugs rather than another drug and/or another generic Valsartan manufactured by another entity.

175. Plaintiff and/or Plaintiff's physicians would not have decided to prescribe and ingest these drugs had they known the true risks associated with them, which was known to Defendants at all relevant times.

176. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

177. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

178. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

IX. NEGLIGENT MISREPRESENTATION

179. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

180. At all relevant times, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, producing, packaging, advertising, distributing, and selling Valsartan, and in fact did sell these drugs to Plaintiff.

181. Specific defects identified herein rendered Defendants' Valsartan defective, unsafe, and unreasonably dangerous.

182. In the course of manufacturing and marketing the products, Defendants made untrue representations of material fact and/or omitted material information to Plaintiff, his physicians, and the medical community.

183. Plaintiff and his physicians reasonably relied upon the misrepresentations and/or omissions and were thereby induced to purchase and use Defendants' products. They were justified in their reliance on Defendants' representations and/or material omissions concerning Defendants' products.

184. Plaintiff and his physicians would not have purchased and/or used these products had they known the true safety risks associated with Defendants' products.

185. Defendants were negligent in their untrue representations and/or omissions, in representing that their Valsartan was the generic of Diovan and that it was safe for ingestion, when in fact, it was unsafe, contaminated, not the true generic of Diovan, and unreasonably dangerous

for human consumption.

186. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

187. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts, Plaintiffs suffered injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

188. Defendants' actions and omissions as contained herein show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

X. VIOLATION OF KENTUCKY CONSUMER PROTECTION ACT

189. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein.

190. Defendant is liable to the Plaintiffs pursuant to the Kentucky Consumer Protection Act (hereinafter, "KCPA"). Defendant is and, at all relevant times was, in the business of designing, manufacturing, marketing, distributing, and selling Valsartan, which it represented to be and sold as generic Diovan. Defendant and/or its agents designed, formulated, manufactured, assembled, prepared for sale, distributed, marketed, and/or sold Valsartan, which was in a defective condition unreasonably dangerous when used as intended in the usual and customary manner and contaminated with known carcinogens, NDMA and NDEA.

191. Privity existed between Plaintiffs and Defendant.

192. Defendant violated the KCPA by the use of false and misleading misrepresentations and/or omissions of material fact in connection with the marketing, promotion, and sale of its drugs. Defendant communicated the purported benefits of its Valsartan while failing to disclose the serious and dangerous injuries related to its use, including injuries related to the contamination with known carcinogens, NDMA and NDEA, with the intent that consumers, like Plaintiffs, would rely upon the misrepresentations believing it to be safe for use in the usual and customary manner.

193. Plaintiff, while using the product in the usual and customary manner as it was intended to be used, suffered injuries as a proximate result of Defendant placing the product on the market, which was unreasonably dangerous and defective at the time it was placed on the market by Defendant.

194. As a direct and proximate result of the Defendant's violations of the KCPA, Plaintiff has suffered significant and permanent damages, including but not limited to physical injury, past and future medical expenses, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future. Additionally, Plaintiffs are entitled to recover attorney's fees and punitive damages. Plaintiffs demand a jury trial on all issues contained herein.

195. Defendant's conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

XI. LOSS OF CONSORTIUM

196. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this

Complaint as if fully set forth herein.

197. Plaintiff, Chitiqua Hocker, is, and at all times relevant was, the spouse of Plaintiff, Jeffrey A. Berryman.

198. As a result of the actions and/or omissions of the Defendant set forth above, Plaintiff, Ms. Hocker, has been deprived of the services, assistance, aid, society, love, affection, companionship, and conjugal relationship of her husband, Plaintiff, Jeffrey A. Berryman, and is entitled to recover pursuant to KRS 411.145 for her loss of consortium in addition to her rights at common law.

199. The damages of Plaintiff, Ms. Hocker, exceed the minimum amount required for the jurisdiction of this Court.

200. Defendant's conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, Camber Pharmaceuticals, Inc., Hetero USA, Inc., and The Kroger Company, on each of the above-referenced claims and causes of action, jointly and severally as follows:

a. Judgment against Defendants, Camber Pharmaceuticals, Inc., Hetero USA, Inc., and The Kroger Company, for compensatory damages in an amount in excess of the amount necessary to invoke the jurisdiction of this Court and reasonably calculated to fully compensate Plaintiffs for their damages;

b. Punitive and exemplary damages against Defendants, Camber Pharmaceuticals, Inc.,

Hetero USA, Inc., and The Kroger Company;

c. Reasonable attorneys' fees as provided by law;

d. Costs and expenses of these actions;

e. Pre-judgment and post-judgment and all other interest recoverable;

f. Statutory damages and other relief permitted by governing state law;

g. Such other additional, and other further relief as Plaintiffs may be entitled to in law or in equity.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury as to all claims in Complaint so triable.

Date: May 29, 2019

Respectfully Submitted,
/s/ Jennifer A. Moore
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Ashton Rose Smith
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Counsel for Plaintiffs

JS 44 (Rev. 11/15)

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

Jeffrey A. Berryman, Chitiqua Hocker

(b) County of Residence of First Listed Plaintiff Fayette (KY)
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jennifer A. Moore, Ashton Rose Smith
Moore Law Group, PLLC, 1473 South 4th Street, Louisville, KY 40208; (502)717-4080

DEFENDANTS

Camber Pharmaceuticals, Inc., Hetero USA, Inc., The Kroger Company

County of Residence of First Listed Defendant New Castle (DE)
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 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)*

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

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

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

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

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

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

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

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

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

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

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

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

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

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(a)

Brief description of cause:
Defective pharmaceutical drug Valsartan

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Robert B. Kugler DOCKET NUMBER 1:19-md-2875

DATE 05/29/2019

SIGNATURE OF ATTORNEY OF RECORD Jennifer A. Moore

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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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 the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six 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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Kentucky

Jeffrey A. Berryman,
Chitiqua Hocker

Plaintiff(s)

v.

Camber Pharmaceuticals, Inc.,
Hetero USA, Inc.,
The Kroger Company

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Camber Pharmaceuticals, Inc.
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Jennifer A. Moore
Ashton Rose Smith
Moore Law Group, PLLC
1473 South 4th Street
Louisville, KY 40208

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Kentucky

Jeffrey A. Berryman,
Chitiqua Hocker

Plaintiff(s)

v.

Camber Pharmaceuticals, Inc.,
Hetero USA, Inc.,
The Kroger Company

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Hetero USA, Inc.
W/K Inc. Services, Inc.
3500 South Dupont Hwy.
Dover, DE 19901

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Jennifer A. Moore
Ashton Rose Smith
Moore Law Group, PLLC
1473 South 4th Street
Louisville, KY 40208

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Kentucky

Jeffrey A. Berryman, Chitiqua Hocker *Plaintiff(s)* v. Camber Pharmaceuticals, Inc., Hetero USA, Inc., The Kroger Company *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* The Kroger Company
Corporation Service Company
421 W. Main Street
Frankfort, KY 40601

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Jennifer A. Moore
Ashton Rose Smith
Moore Law Group, PLLC
1473 South 4th Street
Louisville, KY 40208

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

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