IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Frank Trimboli, Plaintiff, v. Torrent Pharmaceuticals, Ltd., Torrent Pharmaceuticals, Inc., Walgreen Co., and DOES 1 through 100, Defendants.	Case Number: _____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

INTRODUCTION

1. Plaintiff, by and through his counsel, alleges on personal knowledge as to himself, and on information and belief as to all other matters, as follows against all Defendants named herein.

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

I. NATURE OF THIS ACTION

3. Plaintiff seeks compensation for injuries and/or death resulting from use of defective prescription losartan containing drugs (hereinafter "LCDs") designed, manufactured, marketed, distributed, packaged, and sold by Defendants.

4. The LCDs at issue in this litigation contained impurities, including, but not limited to, N-Nitroso-dimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), or other nitrosamine compounds.

PARTIES

I. PLAINTIFF

5. At all relevant times, Plaintiff Frank Trimboli was and is a resident of the Village Patchogue, County of Suffolk, in the State of New York.

6. Plaintiff suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with, inter alia, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of their respective LCDs.

II. DEFENDANTS

A. Torrent Entities

Torrent Pharmaceuticals, Ltd.

7. Defendant Torrent Pharmaceuticals, Ltd. is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India,[1] and with an international office located at: Torrent Pharma Inc., 150 Allen Road, Suite 102 Basking Ridge, NJ 07920.[2] [3]

[1] http://www.torrentpharma.com/; http://www.torrentpharma.com/Index.php/site/info/contactUs

[2] http://www.torrentpharma.com/Index.php/site/info/international

[3] Complaint in Biogen International GMBH, et al. v. Torrent Pharmaceuticals LTD, et al. (District Court of Delaware 2017): https://insight.rpxcorp.com/litigation_documents/12754255

Torrent Pharmaceuticals, Inc.

8. Defendant Torrent Pharmaceuticals, Inc. is a corporation with its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, NJ 07920.[4]

9. Upon information and belief, Torrent Pharmaceuticals, Inc. is the United States subsidiary of Defendant Torrent Pharmaceuticals, Ltd. and was responsible for distribution of the LCDs at issue to United States consumers, including Plaintiff.

B. Pharmacy Defendants

Walgreen Co.

10. Defendant Walgreen Co. is a corporation, with its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015 .[5]

11. Defendant Walgreen Co. sold LCDs directly to Plaintiff.

C. Doe Defendants

12. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of DOES 1 through 100, inclusive, are unknown to Plaintiff at this time, who therefore sue defendants by such fictitious names. Plaintiff is informed and believes, and thereon allege, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiff as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiff for the acts and omissions alleged herein below, and the resulting injuries to Plaintiff,

[4] http://www.torrentpharma.com/Index.php/site/info/international.
[5] https://www.walgreens.com/topic/about/company.jsp

and damages sustained by the Plaintiff. Plaintiff will amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

13. Plaintiff is informed and believes, and thereon allege, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE Defendants, and each of them, and at all said times, each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

JURISDICTION AND VENUE

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

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

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the State of Tennessee, and they are all subject to personal jurisdiction in this District.

THE LOSARTAN-CONTAINING DRUGS

17. The medications in question in this case are drugs that Defendants marketed and sold under the name "losartan."

18. Losartan is a generic version of the brand-name medication, Cozaar.

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

20. The drug 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.

21. Losartan can be sold by itself or as a single pill which combines losartan with HCTZ.

22. The drug binds to angiotensin type II receptors (AT1), working as antagonists.

23. The patents for Cozaar in its various forms expired on August 11, 2009.[6]

24. Shortly after the patents for Diovan and Cozaar expired, the FDA began to approve generic versions of the drugs.

I. NDMA

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

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

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[6] https://www.fiercepharma.com/special-report/cozaar-hyzaar-big-patent-expirations-of-2010.
[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.

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

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

29. 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]

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

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

32. 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]

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[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.
[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.

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

34. On July 27, 2018, the FDA put out a press release, explaining the reason for its concern regarding the presence of NDMA found in losartan-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]

35. 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."[15]

II. NDEA

36. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[16]

37. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.[17]

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

39. 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

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[15] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.
[16] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[17] 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.

ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

40. Hematological effects were also reported in animal studies.[18]

41. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[19]

42. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[20]

43. 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."[21]

44. 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.[22]

III. FORMATION OF NITROSAMINES IN THE SUBJECT DRUGS

45. NDMA and NDEA are both considered genotoxic compounds, as they both contain nitroso groups, which are gene-mutating groups.[23]

46. Upon information and belief, the reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have. Solvents

[18] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[19] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[20] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).
[21] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[22] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[23] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

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.[24]

47. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[25]

IV. RECALLS

48. Upon information and belief, Plaintiff states that the presence of NDMA and NDEA in the LCDs drugs is due to a manufacturing change that took place on or around 2012.[26]

A. U.S. Recalls

49. On November 9, 2018, FDA announced the first recall of LCDs due to the presence of NDEA.

50. Additional losartan recalls continued to follow this announcement and continue through the time of the filing of this Complaint.

51. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of losartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and

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

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."[27]

52. These recalls have continued through the first half of 2019.

B. Recalls in Other Countries

53. The European Medicines Agency (EMA) also recalled many batches of losartan-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."[28]

54. On March 9, 2019, Health Canada issued a recall for a number of LCDs, due to nitrosamine impurities.[29]

THE FEDERAL REGULATORY LANDSCAPE

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

55. 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**

[27] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[28] https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.
[29] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69272a-eng.php

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."[30]

56. 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.[31]

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

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

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

58. 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.[32]

59. 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.[33]

II. MISBRANDED AND ADULTERATED DRUGS

60. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[34]

61. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[35]

62. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[36]

63. 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;"[37]

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

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

[34] 21 U.S.C. § 331(g).

[35] 21 U.S.C. § 331(a).

[36] 21 U.S.C. § 331(c).

[37] 21 U.S.C. § 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;"[38]

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."[39]

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."[40]

64. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[41]

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."[42]

[38] 21 U.S.C. § 351(a)(2)(B).
[39] 21 U.S.C. § 351(b).
[40] 21 U.S.C. § 351(d).
[41] 21 U.S.C. § 352(a)(1).
[42] 21 U.S.C. § 352(c).

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[43]

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…."[44]

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."[45]

f. "if it is an imitation of another drug;"[46]

g. "if it is offered for sale under the name of another drug."[47]

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."[48]

i. If the drug is advertised incorrectly in many manner;[49] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[50]

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

[43] 21 U.S.C. § 352(e)(1)(A)(ii)
[44] 21 U.S.C. § 352(f).
[45] 21 U.S.C. § 352(g).
[46] 21 U.S.C. § 352(i)(2).
[47] 21 U.S.C. § 352(i)(3).
[48] 21 U.S.C. § 352(j).
[49] 21 U.S.C. § 352(n).
[50] 21 U.S.C. § 352(p).

III. THE DRUGS INGESTED BY PLAINTIFF WERE NOT LOSARTAN, BUT NEW, UNAPPROVED, LOSARTAN-CONTAINING DRUGS

66. 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.[51]

67. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[52]

68. 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.

69. FDA further requires that whenever a new, active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New Drug

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[51] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

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

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.[53]

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).

70. 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.*

71. 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.

72. 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.

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

74. 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.[54] Thus, a

[53] *See* 21 C.F.R. § 310.3(h).
[54] *See generally*, https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

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.

75. 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.

76. Because the LCDs 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 LOSARTAN-CONTAINING DRUGS

77. 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,"[55] and conform to requirements governing the appearance of the label.[56]

78. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, [57] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

79. "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."[58]

80. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[59]

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[55] 21 C.F.R. § 201.5.
[56] 21 C.F.R. § 801.15.
[57] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[58] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

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

82. It is unlawful to introduce a misbranded drug into interstate commerce.[60] Thus, the losartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

VI. ADHERENCE TO GOOD MANUFACTURING PRACTICES

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

84. 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.

85. 21 C.F.R. § 210.1(a) states that the cCMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, 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." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

86. 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

[59] 21 C.F.R. § 201.6; 201.10.
[60] 21 U.S.C. § 331(a).

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."

87. 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.

88. 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.

89. 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.

90. 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.

91. 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).

92. 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."

93. Section 211.80 requires an entity to maintain procedures, in relevant part, to sample and test components and drug products, as well as to accept or reject these items for purity, strength, and quality.

94. Part 211.84 further provides, "Representative samples of each shipment of each lot shall be collected for testing or examination," and "[e]ach lot of components…shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit."

95. Specifically, Section 211.90(d)(1) requires, "[a]t least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used."

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

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

98. 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.

99. 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.

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

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

PLAINTIFF'S INJURIES

102. Plaintiff was prescribed and took LCDs during the time in which Defendants' LCDs were contaminated with NDMA, NDEA, or other nitrosamines.

103. The LCDs ingested by Plaintiff were designed, manufactured, marketed, sold, and/or distributed by the above-captioned defendants.

104. As a result of Plaintiff's ingestion of the LCDs, Plaintiff developed and was diagnosed with colon cancer on or around September 2016.

I. CAUSATION

105. Plaintiff would not have consented to taking the LCDs at issue, had Plaintiff known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs, which were rendered unreasonably dangerous by the presence of NDMA, NDEA, and/or other nitrosamines.

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

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

108. Plaintiff and Plaintiff's physicians chose to take and prescribe the LCDs 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. PLAINTIFF'S RESULTING DAMAGES AND INJURIES

109. 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.

110. 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.

111. As a result of use of contaminated losartan 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

112. Plaintiff had no reason until recently to suspect that his 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 LCDs caused Plaintiff's injuries (or that Plaintiff's LCDs were

contaminated at all). For these reasons, Plaintiff's Complaint is filed within the time period allowed by the applicable statutes of limitations.

113. Plaintiff herein brings these actions 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 her injuries and/or the wrongful cause thereof.

114. 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.

115. Defendants named herein are estopped from relying on any statute of limitations defense because they continue to downplay and deny reports and studies questioning the safety of contaminated losartan, 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.

116. Defendants performed the above acts, which were and are illegal, to encourage physicians and patients to prescribe and take LCDs in their contaminated and unreasonably dangerous forms.

117. 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

LCDs, particularly when the drugs ceased to be the same as its brand-name counterpart.

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

119. 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.

120. 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.

GENERAL ALLEGATIONS

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

122. At all relevant times, the LCDs ingested by Plaintiff were researched, developed, manufactured, marketed, promoted, advertised, sold, designed and/or distributed by Defendants.

123. Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold, designed and/or distributed the LCDs ingested by Plaintiff as safe and effective treatment for Plaintiff's underlying conditions.

124. Defendants knew, and/or had reason to know, that the LCDs ingested by Plaintiff were defective, unreasonably dangerous, and not safe for the purposes and uses that these Defendants intended.

125. Defendants knew, and/or had reason to know, that the LCDs 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, and other nitrosamines.

I. REPRESENTATIONS

126. Defendants designed, manufactured, labeled, marketed, packaged, distributed, and promoted the LCDs ingested by Plaintiff for treatment of high blood pressure and other indications.

127. Defendants misrepresented, downplayed, and/or omitted the safety risks of the LCDs ingested by Plaintiff to physicians and patients, including Plaintiff and Plaintiff's physicians by failing to identify, test for, and disclose the presence of nitrosamines in their products and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

128. Defendants 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 LCDs ingested by Plaintiff, which contained carcinogenic compounds.

129. Defendants knew and/or should have known that their representations and suggestions to physicians that their losartan-containing 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.

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

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

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

133. 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.

134. Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the use of the LCDs 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.

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

136. Defendants knew or should have known that it is the duty of all entities in the chain of manufacture and distribution to test its products to ensure they meet quality and safety standards. Yet, Defendants failed to do so.

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

CLAIMS FOR RELIEF

I. STRICT LIABILITY- MANUFACTURING DEFECT

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

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

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

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

142. At all relevant times, the medications ingested by Plaintiff further contained manufacturing defects, in that they were not bioequivalents to Cozaar, thereby rendering these products unreasonably dangerous to patients such as Plaintiff.

143. Defendants were required to manufacture a drug that conformed to FDA-approved specifications, such that the drugs manufactured were equal substitutes to

their brand-name equivalent, Cozaar, which did not contain nitrosamines. These drugs were required to be biologically the "same as an already marketed brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[61]

144. Defendants failed to meet the requirements mentioned in the paragraph above by utilizing a flawed and unlawful manufacturing process that was unvalidated and unsafe and by violating Current Good Manufacturing Practices.

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

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

147. 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

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

149. Defendants had a duty to warn Plaintiff and Plaintiff's physicians about the true risks and benefits of the LCDs 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.

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

150. Specifically, these Defendants should have warned Plaintiff and Plaintiff's physicians about the risks of ingesting NDMA, NDEA, or other nitrosamines at levels which exceeded thresholds deemed to be safe by state and federal governments throughout the United States and the rest of the world.

151. 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.

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

153. The Defendants breached their duty by failing to warn Plaintiff and his physicians of the specific risks and benefits of using their drugs.

154. 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.

155. The warnings and instructions accompanying the LCDs 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.

156. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to use of the LCDs ingested by Plaintiff.

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

158. Plaintiff and his physicians would not have prescribed and taken these LCDs had they known of the true safety risks related to their use.

159. 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

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

161. For the reasons described herein, the LCDs ingested by Plaintiff were adulterated and unreasonably dangerous, as they contained carcinogenic active ingredients, namely NDMA, NDEA, and/or other nitrosamines.

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

163. 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.

164. The LCDs 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.

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

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

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

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

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

IV. NEGLIGENCE

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

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

172. 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.

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

174. 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.

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

V. NEGLIGENCE PER SE

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

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

178. The LCDs ingested by Plaintiff were designed, manufactured, sold, and distributed in violation of federal and state common law, as these drugs never received FDA approval before being marketed and sold to Plaintiff's physician and Plaintiff.

179. 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.

180. 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 LCDs to Plaintiff and Plaintiff's physicians.

181. 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.

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

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

184. 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.

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

186. Thus, for violation of federal law, including the CGMP and 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.

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

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

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

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

VI. BREACH OF EXPRESS WARRANTY

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

192. 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.

193. Through these representations, Defendants made express warranties that these losartan-containing would conform to the representations. More specifically, Defendants represented that these drugs, when ingested by Plaintiff 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.

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

195. 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.

196. 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 active ingredients not disclosed in the product labeling.

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

198. 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 its unreasonable dangers.

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

200. 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

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

202. The LCDs 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.

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

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

205. 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.

206. As a direct and proximate result of Defendants' acts and omissions, Plaintiff ingested these unapproved and unreasonably dangerous losartan-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 are entitled to compensatory, special, and equitable damages in an amount to be proven at trial.

VIII. FRAUD

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

208. 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.

209. Upon information and belief, Defendants were aware that their drugs contained dangerous and carcinogenic compounds, namely NDMA, NDEA, and/or other nitrosamines.

210. 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 losartan-containing drugs for the uses intended by these Defendants; namely, that these drugs contained unsafe levels of NDMA, NDEA, and/or other nitrosamines.

211. 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.

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

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

214. Plaintiff 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.

215. Defendants knew that they were concealing and/or misrepresenting true information about the comparative risks and benefits of the losartan-containing drugs and the relative benefits and availability of alternate products, treatments and/or therapies.

216. 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 losartan-containing drugs for the purposes and in the manner intended by these Defendants.

217. 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.

218. 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 LCDs in deciding to prescribe and ingest these drugs.

219. 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 losartan-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

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

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

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

223. 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.

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

225. 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.

226. 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.

227. 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.

228. 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.

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

X. BREACH OF CONSUMER PROTECTION STATUTES

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

231. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they failed to adequately warn consumers and the medical community of the safety risks associated with the losartan-containing drugs ingested by Plaintiff and when they falsely marketed the drugs taken by Plaintiff as generic versions and bio-equivalents of Diovan.

232. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

233. Defendants have engaged in unfair competition or unfair or deceptive acts or practices.

234. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of losartan-containing drugs and the above described course of fraudulent

conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

235. Plaintiff and his physicians relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe the losartan-containing drugs.

236. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

237. As a direct and proximate result of Defendants' conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

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

XI. PUNITIVE DAMAGES

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

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

241. Defendants failed to conduct proper quality control on their manufacturing processes, such that the product they produced resulted in an entirely new and unapproved drug with undisclosed active ingredients, namely NDMA and/or NDEA.

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

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

244. NDMA, NDEA, and other closely related nitrosamines have been known carcinogens for years.

245. Defendants failed to adequately test the product they were manufacturing, marketing, distributing, repackaging, and selling to doctors and patients, like Plaintiff and Plaintiff's physicians. This inadequate testing went on for years, such that pills containing unreasonably dangerous and carcinogenic substances were distributed to millions of American consumers, as well as consumers throughout the world.

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

247. As a result of Defendants' failure to disclose the ingredients of these drugs, their failure to conduct proper testing, their failure to have adequate quality control measures in place, as well as other actions mentioned in this Complaint, Defendants made millions of dollars.

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for relief and demand judgment against Defendants, and each of them, individually, jointly and severally at trial and request 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: 8/31/2019

Respectfully Submitted,

/s/ Hunter J. Shkolnik
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