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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LOUIS VERDUZCO, MICHAEL EWALD, and FRANCES MARY EWALD

Plaintiffs,

v.

DAIICHI SANKYO, INC., d/b/a Daiichi Sankyo Pharma Development, Daiichi Sankyo Research Institute; f/k/a Daiichi Pharmaceutical Corporation, Sankyo Pharma, Inc., Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., Daiichi Pharma Holdings, Inc.

and

DAIICHI SANKYO US HOLDINGS, INC., parent company of Daiichi Sankyo, Inc.,

and

DAIICHI SANKYO CO., LTD., parent corporation of Daiichi Sankyo US Holdings, Inc. and/or Daiichi Sankyo, Inc.; f/k/a Sankyo Company, Ltd, Daiichi Pharmaceutical Company, Ltd.;

and

CASE NO. 3:15-cv-159

COMPLAINT

DEMAND FOR JURY TRIAL

FOREST LABORATORIES, INC.,
and
FOREST PHARMACEUTICALS, INC.,
and
FOREST RESEARCH INSTITUTE, INC.,

Defendants.

COMPLAINT

Plaintiffs, Louis Verduzco, Michael Ewald, and Frances Mary Ewald, by and through their undersigned counsel, bring this Complaint against the above-named Defendants (collectively referred to as "Defendants" hereinafter), and allege as follows:

INTRODUCTION

Plaintiffs, Louis Verduzco, Michael Ewald, and Frances Mary Ewald bring this action for personal injuries suffered by Plaintiffs as a proximate result of Benicar® being prescribed and ingesting the defective and unreasonably dangerous pharmaceutical blood pressure drug containing the drug *olmesartan medoxomil*, which is, and was at all times relevant to this action, manufactured, designed, researched, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein.

PARTIES

Plaintiffs

1. Plaintiffs Louis Verduzco is a resident of Oakland, California.

2. Michael Ewald and Frances Mary Ewald are residents of Bakersfield, California.

3. Plaintiffs claim and allege that their damages and injuries are the direct and proximate result of Defendants' negligent, intentional, and wrongful acts, omissions, and conduct regarding Defendants' design, development, formulation, manufacture, testing, packaging, labeling, promotion, advertising, marketing, distribution and sale of products containing the drug *olmesartan medoxomil*.

Defendants

A. Daiichi Sankyo Defendants

4. On information and belief, Defendant Daiichi Sankyo, Inc. ("Daiichi Sankyo U.S.") is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business located at Two Hilton Court, Parsippany, New Jersey 07054.

5. On information and belief, Daiichi Sankyo U.S. is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., and Daiichi Pharma Holdings, Inc.

6. On information and belief, Daiichi Sankyo U.S. is in the business of designing, marketing, researching, distributing, packaging, marketing, promoting and selling pharmaceutical drugs across the United States, including within the State of California.

7. On information and belief, Daiichi Sankyo U.S. has a development and regulatory group named Daiichi Sankyo Pharma Development with offices in Edison, New Jersey, and a research institute named Daiichi Sankyo Research Institute with offices in Edison, New Jersey.

8. On information and belief, Daiichi Sankyo U.S. Holdings, Inc. is a Delaware corporation and has a principal place of business at Two Hilton Court, Parsippany, New Jersey 07054.

9. On information and belief, Daiichi Sankyo U.S. is a wholly owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc.

10. On information and belief, Daiichi Sankyo U.S. Holdings, Inc. operates as a holding company for Daiichi Sankyo Co., Ltd.

11. On information and belief, Defendant Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo Japan") is and was at all relevant times a corporation organized and existing under the laws of Japan, having a place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

12. On information and belief, Daiichi Sankyo Japan is in the business of designing and manufacturing prescription drugs across the world, including in the United States and specifically within the State of California.

13. On information and belief, Daiichi Sankyo Japan was formed by a merger between Daiichi Pharmaceutical Company, Ltd., and Sankyo Company, Ltd.

14. On information and belief, Daiichi Sankyo Japan is or was the parent company of Daiichi Sankyo U.S. and/or Daiichi Sankyo U.S. Holdings, Inc., and therefore liable for any and all tort liabilities of Defendants Daiichi Sankyo U.S. and/or Daiichi Sankyo U.S. Holdings, Inc.

15. On information and belief, Daiichi Sankyo U.S. operates as the U.S. headquarters of Daiichi Sankyo Japan. At least four of the principals, members, directors, or officers of Daiichi Sankyo U.S. are also members of Daiichi Sankyo Japan. In addition, Daiichi Sankyo Japan operates several research and development facilities across the world, including collaborating with the Daiichi Sankyo U.S. to oversee global clinical trials from its headquarters in Edison, New Jersey.

16. There existed, at all relevant times to this action, a unity of interest in ownership between Daiichi Sankyo Japan and Daiichi Sankyo U.S., such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these two Defendants, and each of them are the alter egos of one another and exerted direct and control over each other. Adherence to the fiction of a separate and independent existence among the two Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon the plaintiffs and other consumers of their products containing *olmesartan medoxomil*, and promote injustice. The two Defendants, and each of them, condoned and ratified the negligent, willful, intentional, and wrong acts, omissions, and conduct of each other.

17. For convenience purposes, Daiichi Sankyo Japan, Daiichi Sankyo U.S., and Daiichi Sankyo U.S. Holdings, Inc., are hereinafter collectively referred to as “Daiichi Sankyo.”

18. On information and belief, Daiichi Sankyo designs and manufactures numerous pharmaceutical drugs for sale and use through the United States, including within the State of California.

19. On information and belief, Daiichi Sankyo designed, manufactured, packaged, labeled, distributed, sold, marketed, advertised, and/or promoted the blood pressure drugs containing *olmesartan medoxomil*, which is marketed in the United States as Benicar®, Benicar HCT®, Azor®, and Tribenzor®. Daiichi Sankyo refers to these drugs collectively as the "Benicar Family."

B. Forest Defendants

20. On information and belief, Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022. Forest Labs is in the business of manufacturing, distributing, marketing or promoting numerous pharmaceutical drugs for sale and use throughout the United States, including within the State of California.

21. On information and belief, Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") is incorporated in Delaware with its principle place of business located at 13600 Shoreline Drive, St. Louis, Missouri. At all times relevant to this action, Defendant Forest Pharmaceuticals is and has been a division and wholly owned subsidiary of Forest Labs responsible for the manufacture, distribution, and sales of prescription medicine for Forest Labs. Forest Pharmaceuticals has at least eight offices in New York and regularly transacts business within the State of California.

22. On information and belief, Forest Research Institute, Inc. ("FRI"), is a wholly-owned subsidiary of Forest Laboratories, Inc., and was and still is a corporation duly existing under and virtue of the laws of the State of New Jersey with its principal place of business at Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times hereinafter mentioned, Defendant FRI was and still is a pharmaceutical entity involved in research, development, testing, manufacture, production, promotion, distribution and marketing

of pharmaceuticals for distribution, sale and use by the general public of drug medicine, throughout the United States, and within the State of California.

23. There existed, at all relevant times to this action, a unity of interest in ownership between Forest Labs, Forest Pharmaceuticals, and FRI, such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these two Defendants, and each of them are the alter egos of one another and exerted direct and control over each other. Adherence to the fiction of a separate and independent existence among the three Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon the plaintiffs and other consumers of the *olmesartan medoxomil* products, and promote injustice. The three Defendants, and each of them, condoned and ratified the negligent, willful, intentional, and wrong acts, omissions, and conduct of each other.

24. For convenience purposes, Defendants Forest Labs, Forest Pharmaceuticals and FRI are hereinafter referred collectively as "Forest."

25. On information and belief, Defendants Forest and Daiichi Sankyo entered an expense and profit sharing relationship in exchange for the co-promotion of blood pressure drugs containing *olmesartan medoxomil*, including but not limited to Benicar®, Benicar HCT®, and Azor®.

26. On information and belief, Forest profited from these drug products, receiving 45 percent of Benicar profits for several years in exchange for its co-promotion of the products.

C. <u>All Defendants</u>

27. The term "Defendants" is used hereafter to refer to all the entities named above.

28. Defendants are corporations organized under the laws of various states of the United States of America or the Dominion of Japan that were or are doing business within the State of California. The aforementioned Defendants designed, marketed, sold, distributed, packaged, promoted, labeled, researched, tested or manufactured the *olmesartan medoxomil* product(s) which Plaintiffs ingested.

29. At all times relevant to this action, all Defendants and each of them were in the capacity of the principal or agent of all of the other Defendants, and each of them, and acted

within the scope of their principal and agent relationships in undertaking their actions, conduct, and omissions alleged in this Complaint. All Defendants, and each of them, acted together in concert or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of reaping substantial monetary profits from the sale of the *olmesartan medoxomil* products and for the purpose of enriching themselves financially to the serious detriment of Plaintiffs' health and wellbeing.

JURISDICTION AND VENUE

30. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

31. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

32. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of marketing prescription drug products, including the *olmesartan medoxomil* products, within the State of California, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

33. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of promoting prescription drug products, including the *olmesartan medoxomil* products, within the State of California, with a reasonable expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

34. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of distributing prescription drug products, including the *olmesartan medoxomil* products, within the State of California, with a reasonable expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

35. At all times relevant to this action, the Defendants have been engaged either directly or indirectly, in the business of selling prescription drug products, including the *olmesartan medoxomil* products, within the State of California, with a reasonable expectation that the products would be used or consumed in this state, and thus have regularly solicited or transacted business in this state.

36. At all times relevant to this action, the Defendants were engaged in disseminating inaccurate, false, and misleading information about the *olmesartan medoxomil* products to physicians in all states in the United States, including the State of California, with a reasonable expectation that the misleading information would be used and relied upon by physicians throughout the United States, including the State of California.

37. This court has personal jurisdiction over Daiichi Sankyo Japan based on its contacts with California relating to the subject matter of this action and because Daiichi Sankyo Japan has continuous and systematic contacts with this judicial district. On information and belief, Daiichi Sankyo Japan regularly places goods into the stream of commerce for distribution in California and throughout the United States. Members of Daiichi Sankyo Japan continuously communicate from Japan with members of Daiichi Sankyo U.S., who include officers, members, directors or principals who are from Daiichi Sankyo Japan.

38. This court has personal jurisdiction over Forest Labs based on its contacts within the State of California relating to the subject matter of this action and because Forest Labs has continuous and systematic contacts with this judicial district. Among other things, Forest Labs entered co-marketing agreements with Daiichi Sankyo relating the *olmesartan medoxomil* products in this action.

39. This court has personal jurisdiction over Forest Pharmaceuticals based on its contacts within the State of California relating to the subject matter of this action and because Forest Pharmaceuticals has continuous and systematic contacts with this judicial district. Among other things, Forest Pharmaceuticals entered co-marketing agreements with Daiichi Sankyo relating the olmesartan products in this action.

40. Venue is proper in this district because the Defendants are doing business within the State of California, including the sale, marketing, promotion and distribution of the olmesartan products relevant to this action. In addition, Plaintiff Verduzco resides in this District and ingested olmesartan in this District.

FACTUAL BACKGROUND

41. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

42. At all times relevant to this action, Defendants acted through their respective officers, employees and agents, who in turn were acting within the scope of their authority and employment in furtherance of the business of the Defendants.

***Olmesartan* Products**

43. On information and belief, Daiichi Sankyo Japan is the owner of the United States Letters Patent No. 5,616,599 ("the '599 patent"). The '599 patent claims various chemical compounds including *olmesartan medoxomil* specifically, as well as pharmaceutical compositions containing these compounds, and method for the treatment or prophylaxis of hypertension administering these compounds.

44. On information and belief, *olmesartan medoxomil* is classified as an angiotension II receptor blocker ("ARB"). *Olmesartan medoxomil* was the seventh commercialized ARB monotherapy product brought to the market.

45. On information and belief, the '599 patent was assigned by the inventors to Daiichi Sankyo Japan and remains assigned to Daiichi Sankyo Japan.

46. On information and belief, Daiichi Sankyo U.S. is a licensee under the '599 patent and is marketing and selling pharmaceutical drugs containing *olmesartan medoxomil* that are manufactured by Daiichi Sankyo Japan throughout the United States, including within the State of California.

47. On information and belief, Daiichi Sankyo U.S. holds an approved new drug application ("NDA") No. 21-286 for Benicar® tablets (5 mg, 20 mg, and 40 mg), which tablets contain the active ingredient *olmesartan medoxomil*. Benicar® tablets were approved by the

United Stated Food and Drug Administration ("FDA") on April 25, 2002, for treatment of hypertension.

48. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 21-532 for Benicar HCT® tablets (40/12.5 mg, 40/25 mg, and 20/12.5 mg), which tablets contain the active ingredients *olmesartan medoxomil* and *hydrochlorothiazide*. Benicar HCT® tablets were approved by the FDA on June 5, 2003, for the treatment of hypertension, but are not indicated for initial therapy.

49. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 22-100 for Azor® tablets (5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg), which tablets contain the active ingredients *amlodipine besylate* and *olmesartan medoxomil*. Azor® tablets were approved by the FDA on September 26, 2007 for the treatment of hypertension, alone or in combination with other antihypertensive agents.

50. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 20-0175 for Tribenzor® tablets (40/10/25 mg, 40/5/12.5 mg, 20/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg), which tablets contain the active ingredients *olmesartan medoxomil*, *amlodipine* and *hydrochlorothiazide*. Tribenzor® tablets were approved by the FDA on July 23, 2010, for treatment of hypertension, but are not indicated for initial therapy.

51. The terms "Benicar" and "olmesartan" are frequently and interchangeably employed, in common usage among the medical community, to refer to all or any of the *olmesartan medoxomil* products, including the specific U.S. brand name products Benicar®, Benicar HCT®, Azor®, and Tribenzor®.

52. On information and belief, Daiichi Sankyo is or was referring to its *olmesartan medoxomil* products as the "Benicar Family."

53. For convenience purposes, the *olmesartan medoxomil* products sold by Defendants are hereinafter collectively referred to as "olmesartan products."

54. As required by law for all prescription drug products, each of the Defendants include the product's "labeling," as approved by the FDA, on labels, also called "package inserts," placed on or in the packages from which the products were to be dispensed from

pharmacies, or from which "product samples," if any, were to be dispensed by doctors. The labeling includes information on the product's active and inactive ingredients, clinical pharmacology, "indications" and usage, contraindications, warnings, precautions, and side effects (adverse reactions and overdosage).

55. The "indications" or "indicated" uses for the olmesartan products, as reflected in the product labeling, included for treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure.

56. The text of the "indications" or "indicated" uses for the olmesartan products, did not disclose any risks associated with long-term use of the drug.

57. The package inserts for the olmesartan products are materially identical to the "monograph" for the olmesartan products published in the Physician's Desk Reference.

58. In connection with all of the olmesartan products, Plaintiffs allege the following:

FDA Drug Safety Communication and Label Change

59. On July 3, 2013, the FDA issued a Drug Safety Communication warning that the blood pressure drug *olmesartan medoxomil*, marketed as Benicar®, Benicar HCT®, Azor®, and Tribenzor®, can cause intestinal problems known as sprue-like enteropathy. The FDA approved changes to the label of these drugs to include this concern. Some of the findings of the FDA include but are not limited to:

a. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss.

b. The enteropathy may develop months to years after starting olmesartan medoxomil, and sometimes require hospitalization.

c. If patients taking olmesartan develop these symptoms and no other cause is found, the drug should be discontinued, and therapy with another antihypertensive started.

d. Discontinuation of olmesartan has resulted in clinical improvement of sprue-like enteropathy symptoms in all patients.

e. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan.

f. In 2012, a total of approximately 1.9 million patients received a dispensed prescription for olmesartan-containing products from U.S. outpatient retail pharmacies.

g. The FDA identified 23 serious cases in the FAERS presenting as late-onset diarrhea with significant weight loss and, in some cases, with intestinal villous atrophy on biopsy. All patients improved clinically after discontinuation of *olmesartan medoxomil*, and a positive rechallenge was seen in 10 of the cases.

h. In June 2012, Mayo Clinic researchers published a case series of sprue-like enteropathy associated with olmesartan in 22 patients whose clinical presentation was similar to that of the FAERS cases.

i. In May 2013, an article describing patients with villous atrophy and negative serologies for celiac disease reported that some patients without definitive etiologies from villous atrophy were characterized as having unclassified sprue. Some of these patients were subsequently found to have villous atrophy associated with olmesartan use.

j. The FDA further investigated the signal of sprue-like enteropathy with olmesartan for a possible ARB class effect using active surveillance data. The FDA found that olmesartan users had a higher rate of celiac disease diagnoses in claims and administrative data than users of other ARBs. Interpretation is limited by the small number of events observed at longer exposure periods and the uncertainty about the validity of codes for celiac disease, but these results support other data in suggesting a lack of a class effect.

k. Findings of lymphocytic or collagenous colitis and high association with HLA-DQ2/8 suggest a localized delayed hypersensitivity or cell-mediated immune response to *olmesartan medoxomil*.

60. The Defendants knew, or by the reasonable and careful employment of known scientific methods could have known, and, in the exercise of reasonable care toward patients who would be expected to ingest the olmesartan products, should have known, *inter alia*, that:

a. Studies published in peer-reviewed scientific and medical literature found there may be an association between olmesartan and sprue-like enteropathy;

b. These studies represent the best scientific evidence available for evaluating the association between olmesartan and intestinal problems, including sprue-like enteropathy;

c. Physicians commonly prescribe olmesartan as treatment for hypertension for prolonged periods of six months to a year or more;

d. Clinical trials for the olmesartan drug lasted up to three months in duration;

e. Sprue-like enteropathy are typically and often experienced chronically over long periods of time; and/or

f. Clinical trials over periods greater than three months would reveal the effects of longer term cumulative exposure to olmesartan.

FDA Investigates Risk of Cardiovascular Events

61. In 2010, the FDA issued a Drug Safety Communication announcing that the agency is evaluating data from two clinical trials in which patients with type 2 diabetes taking olmesartan had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. The Agency planned to review primary data from the two studies of concern, and was considering additional ways to assess the cardiovascular effects of Benicar®.

62. In 2011, the FDA issued a safety review update as a follow-up to the 2010 FDA Safety Communication. After reviewing the results of these clinical trials, the FDA determined that the benefits of Benicar® continue to outweigh its potential risks when used for treatment of patients with high blood pressure according to the drug label. Benicar® is not recommended as a treatment to delay or prevent protein in the urine (microalbuminuria) in diabetic patients. Daiichi Sankyo agreed to work with the FDA to perform additional studies, as well as conduct additional analyses of completed clinical studies, to obtain more complete information about the cardiovascular risks or benefits of Benicar® in various clinical settings. The FDA will update the public when new information is available.

63. On information and belief, these studies were submitted on a delayed basis to the FDA.

Defendants' False and Misleading Advertising and Omission and Minimization of Risk Information

64. On information and belief, Daiichi Sankyo spent $1 billion dollars in "promotional spending" between 2002 and 2008 for Benicar® and Benicar HCT®.

65. At all times relevant to this action, Daiichi Sankyo's olmesartan products were the third highest selling ARB products available on the U.S. market.

66. The U.S. market for hypertension treatment is massive. Approximately 73 million people in the United States age 20 and older have hypertension, about 61 percent of which (or 45 million) are under treatment.

67. On information and belief, Daiichi Sankyo invested heavily in face-to-face meetings with physicians, physician meeting events, and clinical samples to promote its olmesartan products.

68. On information and belief, the olmesartan products were sold as part of a co-promotion agreement with Forest, a recognized United States pharmaceutical company.

69. On information and belief, the Defendants launched in 2002 an aggressive marketing campaign focused on convincing physicians that Benicar® was the "ARB with superior efficacy and more."

70. On information and belief, Daiichi Sankyo and Forest distributed marketing materials to physicians and other consumers claiming that its olmesartan products were superior, more effective, and safer than other antihypertensive drug products available.

71. In 2006, the FDA found Daiichi Sankyo and Forest's efficacy and safety claims unsubstantiated and false or misleading. According to the FDA and contrary to Daiichi Sankyo's marketing claims, there was no evidence that Benicar was superior to, safer than, or more effective than other ARBs. The FDA also found that Daiichi Sankyo and Forest's marketing materials failed to include risk information necessary to qualify its safety and effectiveness claims presented for Benicar® and Benicar HCT®. In addition to omitting important risks from the PI, the materials also minimized the risks it did present and misleadingly signals to the reader that the risks that are presented are minimal in nature.

72. The FDA ordered Daiichi Sankyo and Forest to cease making these superiority and efficacy claims and to take corrective measures. The corrective measures included discontinuing use of approximately fifty promotional pieces dated all the way to 2002 and dissemination of corrective messages to physicians who received the materials.

73. The promotional materials that were discontinued included but not limited to product monographs that are the full prescribing information for a product, posters, and hospital displays.

74. In 2013, the FDA reviewed a professional Direct Mail for Benicar and Benicar HCT tablets submitted by Daiichi Sankyo. The FDA found the promotional material misleading because it makes unsubstantiated efficacy claims associated with Benicar and Benicar HCT in violation of the Federal Food, Drug and Cosmetic Act. Promotional materials are considered misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

75. The FDA requested that Daiichi Sankyo immediately cease the dissemination of violative promotional materials for Benicar and Benicar HCT.

Efficacy of Olmesartan Products

76. At all times relevant to this action, Daiichi Sankyo did not conduct any clinical outcome trials that would prove that *olmesartan medoxomil* is effective in treating conditions associated with the long-term risks of hypertension. In contrast, five of the seven ARBs have performed clinical outcome trials with the long-term risks of hypertension, such as heart failure, stroke and renal nephropathy in patients with Type 2 diabetes mellitus.

77. On information and belief, Daiichi Sankyo's internal documentation references a lack of clinical data still existing as of 2007.

78. On information and belief, Daiichi Sankyo continues to lack such clinical data in all times relevant to this action.

Plaintiffs' Ingestion of the Olmesartan Product(s)

79. Plaintiffs were prescribed Benicar® by their treating physicians.

80. Plaintiffs Louis Verduzco and Michael Ewald ingested and used the olmesartan product named Benicar® according to its intended and directed use.

81. While taking the recommended dosage of Benicar®, Plaintiffs Louis Verduzco and Michael Ewald developed personal injuries, including but not limited to severe intestinal and/or colonic disease manifestations including but not limited to sprue-like enteropathy, villous atrophy, lymphocytic colitis, microscopic colitis, collagenous colitis, and/or intestinal malabsorption.

82. The above-named disease manifestations resulted in Plaintiffs Louis Verduzco and Michael Ewald suffering from chronic diarrhea, rapid weight loss, nausea, vomiting, malnutrition, dehydration, and/or acute renal failure.

83. After developing these injuries, Plaintiffs Louis Verduzco and Michael Ewald were hospitalized suffering from chronic diarrhea, acute renal failure, severe anemia, weakness, nausea, and/or weight loss.

84. It was and is necessary for Plaintiffs Louis Verduzco's and Michael Ewald's medical conditions to be monitored by physicians and other health care providers to determine sequelae associated with intestinal and/or colonic disease manifestations, as well as severe chronic diarrhea, rapid and substantial weight loss, severe malnutrition, severe dehydration, and/or acute renal failure.

85. Plaintiffs Louis Verduzco's and Michael Ewald's medical conditions necessitated screening, testing, and treatment performed by physicians and other health care providers, which have required and will require Plaintiffs to be continually monitored for sequelae associated with such screening, testing, and treatment.

86. Plaintiffs Louis Verduzco and Michael Ewald have suffered unavoidable, serious and life threatening physical injuries, severe emotional distress, and mental injuries in coping with their physical injuries, and have incurred and expended significant amounts for the medical care, hospitalizations, and medications, required to treat and care for olmesartan-related disease, pain, and suffering and will continue to do so long into the future.

87. Plaintiffs file this lawsuit within the applicable statute of limitations period of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering the cause of their injuries and the wrongful conduct that caused such injuries. Plaintiffs could not by exercise of reasonable diligence have discovered any wrongdoing, nor could have discovered the causes of their injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiffs' injuries were discovered, their causes were not immediately known. Most, if not all, patients with olmesartan-related intestinal and colonic manifestations, go for months or even years treating with multiple physicians, undergoing testing, being misdiagnosed, and receiving ineffective treatments before finally being properly diagnosed. Further, the relationship of Plaintiffs' injuries to olmesartan exposure through the Defendants' products was inherently difficult to discover. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs discover, or by the exercise of reasonable diligence should have discovered, that Plaintiffs may have a basis for an actionable claim.

CAUSES OF ACTION

CLAIMS ASSERTED BY ALL PLAINTIFFS

88. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

89. The Plaintiffs were prescribed, purchased, or was injured as a result of ingestion of the olmesartan products within the state of California. To the extent the court chooses to apply the law of a state other than California, Plaintiffs intend to put Defendants on notice of all claims which may be asserted by the individual Plaintiffs from other states and jurisdictions in addition to California.

COUNT I
PRODUCTS LIABILITY – DEFECTIVE DESIGN

90. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

91. At all times relevant to this action, the Defendants engaged in the business of selling, distributing, manufacturing, marketing, and promoting the olmesartan products, which are defective and unreasonably dangerous to consumers, including the Plaintiffs. These actions were under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

92. At all times relevant to this action, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, distributed, or have recently acquired entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the olmesartan product(s) used by Plaintiffs, as described above. These actions are under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

93. At all times relevant to this action, the Defendants expected its olmesartan products to reach and did reach the intended consumers, handlers, and persons coming into contact with these products in this state and throughout the United States, including Plaintiffs, without substantial or material change in they were produced, manufactured, sold, distributed, labeled, and marketed by these Defendants. These actions are under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

94. At all times relevant to this action, the olmesartan products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants were defective in design and formulation, in one or more of the following particulars:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonable safe as intended to be used, subjecting Plaintiffs to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, it was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of hypertension;

c. The drug was insufficiently tested;

d. The drug caused harmful side effects that outweighed any potential utility;

e. The drug was not accompanied by adequate instructions and/or warnings to fully apprise the consumers, including the Plaintiffs, of the full nature and extent of the risks and side effects associated with their uses, thereby rendering the Defendants, are liable to the Plaintiffs, individually and collectively;

f. Defendants also failed to adequately instruct on the length of time an individual should be allowed to continue using the drug;

g. Defendants were aware at the time the olmesartan products were marketed that chronic, long-term intake of the olmesartan products would result in an increased risk of stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, weight loss, hospitalization(s) related to dehydration and malnutrition, vomiting, and/or severe nausea;

h. Defendants were aware at the time that the drug was marketed that chronic, long-term use would result in causing an increased risk of bodily injuries;

i. Inadequate post-marketing surveillance; and/or

j. There were safer alternative designs and formulations that were not utilized.

95. At all times relevant to this action, the Defendants knew or had reason to know that the olmesartan products were in a defective condition, and were inherently dangerous and unsafe when used in the manner instructed and provided by the Defendants.

96. With respect to products they manufactured or sold, Defendants had a duty to create products that were not unreasonably dangerous for their normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

97. At the time of Plaintiffs' use of the olmesartan product(s), it was being used for its intended purpose, and in a manner normally intended.

98. The Plaintiffs could not, by the reasonable exercise of care, have discovered the defects and perceived their danger before ingestion of the olmesartan product(s).

99. Defendants' defective design of the olmesartan products as well as Defendants' past, present, and continuing lack of adequate warnings accompanying the products, are willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users

of the olmesartan products. Defendants' conduct is motivated by greed and the intentional decision to value profits over the safety and wellbeing of the consumers of the olmesartan products.

100. The defects in Defendants' olmesartan product(s) were substantial and contributing factors in causing Plaintiffs' injuries.

101. As a result of the wrongful acts and omissions of Defendants, the Plaintiffs were caused to suffer the serious and dangerous side effects of the product as described herein, and in addition, physical pain and mental anguish, diminished physical abilities and engagement in daily activities, the need for continuing and life-long medical treatment and monitoring, and the reasonable and significant fear of chronic health problems related to their olmesartan product-related injuries, all of which have significantly and detrimentally affected the quality of Plaintiffs' ability to perform and enjoy daily life activities.

102. As a proximate result of Defendants' acts and omissions and Plaintiffs' ingestion of Defendants' defective product, Plaintiffs have suffered serious physical injuries and have incurred substantial medical costs and expenses to treat and care for their injuries described herein. As a further direct and proximate result of Defendants' acts and omissions, Plaintiffs will continue to suffer serious physical and emotional injuries, and will continue to incur significant medical costs and expenses, expend large sums of money to pay for medical care and treatment of their physical injuries, and will continue to suffer economic loss, and physical and emotional injuries.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT II
PRODUCTS LIABILITY – FAILURE TO WARN

103. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

104. The olmesartan products were defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiffs herein, to the dangerous risks and reactions associated with the drug, including stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, nausea, malnutrition, dehydration, and weight loss.

105. The Plaintiffs were administered the olmesartan product(s) for its intended purpose.

106. The Plaintiffs could not have discovered any defect in the olmesartan products through the exercise of care.

107. Defendants, as the manufacturer or distributor of prescription drug products, were responsible for researching, developing, designing, testing, manufacturing, inspecting, labeling, marketing and promoting, the olmesartan products that they respectively distributed, sold and otherwise released into the stream of commerce, and therefore had a duty to adequately earn of the risks associated with the use of their respective products.

108. Defendants had a continuing duty to warn the Plaintiffs of the dangers associated with the olmesartan products.

109. Defendants, as manufacturers, sellers, or distributors of a prescription device, are held to the knowledge of an expert in the field.

110. The dangerous propensities of the olmesartan products, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

111. Each of the Defendants knew or should have known that the limited warnings disseminated with the use of the olmesartan products were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug, in particular failing to communicate to doctors warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and

reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for long term hypertension therapy.

112. Defendants communicated to physicians information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable doctors to prescribe the drug safely for use by his or her patients for the purposes for which it is intended, including commonly employed long term antihypertensive drug therapy. In particular, the Defendants disseminated information that was inaccurate, false and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with such use of olmesartan product; continued to aggressively promote the olmesartan products, even after it knew or should have known of the unreasonable risks from long term use; and overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the minimal warnings it did disseminate.

113. Owing to these deficiencies and inadequacies, the olmesartan products as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants was unreasonably dangerous and defective.

114. The Defendants that manufactured, sold, or distributed the olmesartan products that the Plaintiffs ingested are liable to Plaintiffs for injuries caused by the innocent, negligent or willful failure as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of their respective product and the risks associated with its use.

115. The injuries and losses suffered by Plaintiffs are a direct and proximate result of the conduct of the Defendants. The Plaintiffs have suffered and continue to suffer serious physical, mental and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and

proper.

COUNT III
STRICT LIABILITY

116. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

117. At the time of Plaintiffs' injuries, the olmesartan products were defective and reasonably dangerous to foreseeable consumers, including Plaintiffs.

118. The Plaintiffs bring this claim under the applicable state's common law, including the Restatement of Torts (Second).

119. The olmesartan products ingested by Plaintiffs were in the same or substantially same condition as they were when they left the possession of Defendants.

120. Plaintiffs did not misuse or materially alter the olmesartan products.

121. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. The olmesartan products, as designed, manufactured, sold, distributed, and supplied by Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition causing injury to Plaintiffs;

b. The product defects created a situation that was potentially dangerous to Plaintiffs and other consumers;

c. Defendants failed to properly market, design, manufacture, distribute, supply and sell the olmesartan products;

d. Defendants failed to warn and place adequate warnings and instructions on the olmesartan products;

e. Defendants failed to adequately test the olmesartan products which would have further indicated through a risk/benefit analysis that the product was not fit for its intended use;

f. Defendants failed to provide timely and adequate post-marketing warnings and instructions long after they knew of the risk of injury associated with the use of olmesartan products;

g. A feasible alternative design existed that was capable of preventing Plaintiffs' injuries; and/or

h. Defendants' olmesartan products caused injuries and losses that are of the kind that made each product a basis for strict liability.

122. As a result of Defendants' foregoing acts and omissions, Plaintiffs were or still are caused to suffer or are at a greatly increased risk of serious and dangerous side effects, including, *inter alia*, stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, potential death, as well as the need for lifelong medical treatment, monitoring or medications, and fear of developing any of the above named health consequences and related sequelae.

123. Defendants risked the lives of the consumers of their olmesartan products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge to the general public. Defendants made conscious decisions not to redesign, relabel, warn or inform the unsuspecting consuming public, medical community, or healthcare community.

124. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require healthcare and services, and have incurred medical, healthcare, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care, hospital care, or additional medical services.

125. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for Plaintiffs' well-being, Plaintiffs are entitled to punitive and exemplary damages as well as compensatory damages.

WHEREFORE, Plaintiffs demands judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT IV
GROSS NEGLIGENCE

126. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

127. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and the Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards; was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

128. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

129. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

130. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that will punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and

proper.

COUNT V
NEGLIGENCE AND FAILURE TO WARN

131. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

132. Defendants, directly or indirectly, caused the olmesartan products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiffs.

133. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and/or distribution of the olmesartan products, including the duty to take all reasonable steps necessary to manufacture, promoted and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

134. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed and/or sold the olmesartan products, Defendants knew, or in the exercise of reasonable care should have known, that their products were defective, dangerous, and otherwise highly harmful to Plaintiffs.

135. Defendants knew, or in the exercise of reasonable care should have known, that the use of the olmesartan products could cause or be associated with stomach, intestinal and/or colonic disease manifestations and thus created a dangerous and unreasonable risk of injury to users of the products.

136. Defendants knew from its own investigations, including analysis of sales statistics, adverse event reporting, and/or scientific studies published in peer-reviewed medical journals, that many physicians were unaware of the extent of these risks posed by the olmesartan products.

137. Defendants knew that many physicians were over-prescribing the olmesartan products, and that many patients developed serious side effects, including stomach, intestinal, and/or colonic disease manifestations, chronic diarrhea, weight loss, vomiting, nausea, dehydration, or malnutrition.

138. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of the olmesartan products in interstate commerce, in that Defendants knew and had reason to know that a consumer patient's use and ingestion of the product(s) created a significant risk of suffering unreasonably dangerous health related side effects, including stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and/or dehydration.

139. Defendants were further negligent in that they manufactured produced defective products containing the drug *olmesartan medoxomil*, knew and were aware of the defect inherent in the products, failed to act in a reasonably prudent manner in marketing the products, and failed to provide adequate warnings of the products' defects.

140. Defendants were further negligent and breached their continuing duty of pharmacovigilance with respect to Plaintiffs. Defendants, through clinical trials and other adverse event reports, learned that there were serious problems with the olmesartan products' use and failed to inform physicians, regulatory agencies, and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time the olmesartan products have been on the market in the United States.

141. These physical injuries are severe in nature, including but not limited to physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic illness proximately caused by ingestion of the olmesartan product(s), the continued risk of requiring additional medical or surgical procedures including general anesthesia, with attendant risk of life threatening complications.

142. Defendants' negligence included, but not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and/or distributing the olmesartan products without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the olmesartan products while negligently and/or intentionally concealing and failing to disclose the results of clinical trials and tests regarding use of the olmesartan products, which demonstrated the risk of serious harm associated with the use of olmesartan products;

c. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of the olmesartan products;

d. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the olmesartan products were safe for its intended use;

e. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew or had reason to know that the olmesartan products were indeed unreasonably unsafe and unfit for use by reason of product's defect and risk of harm to its users in the form of intestinal damage and other serious illnesses;

f. Failing to warn plaintiffs, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative antihypertensive medications available to plaintiffs and other consumers;

g. Declining to make or propose any changes to the olmesartan products' labeling or other promotional materials that would alert physicians and the medical community to the risks of the olmesartan products;

h. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume the olmesartan products;

i. Advertising, marketing, and recommending the use of the olmesartan products, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected, associated or caused in the use of the olmesartan products;

j. Representing that the olmesartan products were safe for its intended use when in fact, Defendants knew or should have known that the products were not safe for their intended purpose;

k. Failing to advise physicians, the medical community, or patients taking the olmesartan products, that its statements regarding the safety of its products were inaccurate;

l. Failing to disclose to Plaintiffs and their prescribing physician(s), through the prescribing information for the olmesartan products, about the risk of developing stomach, intestinal, and colonic disease manifestations including but not limited to sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and/or dehydration;

m. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective antihypertensive drugs were available for use to treat hypertension for which the olmesartan products were manufactured;

n. Failing to reference the chronic nature and severity of the adverse reactions provided in its label, including developing stomach, intestinal and colonic disease manifestations including but not limited to sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration;

o. Continuing to disseminate information to physicians which indicate or imply that the olmesartan products are not unsafe for treatment of hypertension;

p. Continuing manufacture and sale of the olmesartan products with the knowledge that the products was unreasonably unsafe and dangerous, and failed to comply with FDA regulations and policy;

q. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the olmesartan products so as to avoid the risk of serious harm associated with the use of the olmesartan products as an antihypertensive medication;

r. Advertising, marketing, promoting and/or selling the olmesartan products for uses other than as approved and indicated in the product's label;

s. Failing to design and manufacture the olmesartan products so as to ensure the products were at least as safe and effective as other antihypertensive drugs on the market;

t. Failing to ensure the products were accompanied by proper and accurate warnings about the possible adverse side effects associated with the use of the olmesartan products and that use created a risk of stomach, intestinal and colonic disease manifestations, including but not limited to sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, that could be life-threatening; and/or

u. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of the olmesartan products.

143. Defendants knew and should have known that it was foreseeable that consumers such as plaintiffs would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturer, marketing, labeling, distribution and sale of the olmesartan products.

144. Plaintiffs do not know the nature and extent of the injuries that would result from ingestion and use of the olmesartan product(s).

145. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiffs have suffered and will continue to suffer into the future.

146. As a result of Defendants' acts and omissions described in this Complaint, Plaintiffs' Louis Verduzco and Michael Ewald were proximately caused to suffer the serious and dangerous side effects of the olmesartan products, including but not limited to stomach, intestinal and colonic disease manifestations, chronic diarrhea, weight loss, nausea, vomiting, dehydration and malnutrition. Plaintiffs also suffered other severe personal injuries as a result of Defendants' acts and omissions, which injuries include, *inter alia*, physical pain and mental anguish, significantly diminished physical abilities and life activities, the need for life-long medical treatment, and medical monitoring for further injuries related to Plaintiffs' ingestion of the olmesartan product(s) and the resulting medical conditions and injury.

147. As a proximate result of Defendants' acts and omissions and Plaintiffs' ingestion of Defendants' defective product, Plaintiffs have suffered serious physical injuries and have

incurred substantial medical costs and expenses to treat and care for their injuries described herein. As a further direct and proximate result of Defendants acts and omissions, Plaintiffs continue to suffer serious and physical and emotional injuries, and will continue to incur significant medical costs and expenses, expend large sums of money to pay for medical care and treatment of their physical injuries, and will continue to suffer economic loss and physical and emotional injuries.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VI
DEFENDANTS' FAILURE TO COMPLY WITH ALL FEDERAL STANDARDS AND REQUIREMENTS APPLICABLE TO THE SALE OF OLMESARTAN PRODUCTS

148. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

149. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, and warning of risks and dangers of the olmesartan products.

150. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse drug experience concerning the olmesartan products that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendants, failing to promptly investigate all adverse drug experiences concerning the olmesartan products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above named

Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

151. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

152. Defendants had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiffs, the truth regarding Defendants' claims that the olmesartan products had been tested and found to be safe and effective for hypertension treatment. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made by Defendants.

153. Defendants failed to exercise ordinary care in making their representations concerning the olmesartan products and their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.

154. Defendants engaged in a campaign of over-promoting the olmesartan products in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of the olmesartan products while concealing, misrepresenting, actively downplaying the serious, severe, and life-threatening risks of harm to users of olmesartan products, when compared to comparable or superior alternative drug therapies

155. Defendants negligently misrepresented the olmesartan products' risk of unreasonable, dangerous, adverse side effects.

156. As a direct and proximate result of Defendants' acts and omissions described herein, and Plaintiffs' ingestion of Defendant's defective product, Plaintiffs have suffered serious physical injuries and have incurred substantial medical costs and expenses to treat and care for their injuries described herein. As a further direct and proximate result of Defendants' acts and omissions, the Plaintiffs will continue to suffer serious physical and emotional injuries, and will

continue to incur significant medical costs and expenses, expend large sums of money to pay for medical care and treatment of their physical injuries, and will continue to suffer economic loss and physical and emotional injuries.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VIII
FRAUDULENT CONCEALMENT

157. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

158. Throughout the relevant time period, Defendants knew that the olmesartan products were defective and unreasonably unsafe for their intended purpose.

159. Defendants fraudulently concealed from or failed to disclose to or warn Plaintiffs, physicians, and the medical community that the olmesartan products were defective, unsafe, unfit for the purposes intended, and that they were not of merchantable quality.

160. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the olmesartan products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the olmesartan products;

b. Defendants knowingly made false claims about the safety and quality of the olmesartan products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the olmesartan products from Plaintiffs.

161. The facts concealed or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the olmesartan products.

162. Defendants intentionally concealed or failed to disclose the true defective nature of the olmesartan products so that Plaintiffs would request and purchase the olmesartan products, and that their healthcare providers would dispense, prescribe, and recommend the olmesartan products, and Plaintiffs justifiably acted or relied upon, to their detriment, the concealed or non-disclosed facts as evidenced by their purchase of the olmesartan products.

163. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians from acquiring material information regarding the lack of safety and effectiveness of the olmesartan products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the olmesartan products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, Restatement (Second) of Torts § 550 (1977).

164. As a result of Defendants' foregoing acts and omissions, Plaintiffs were or still are caused to suffer or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, stomach, intestinal and colonic disease manifestations, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring or medications, and fear of developing any of the above named health consequences.

165. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require healthcare and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care or hospital care and medical services.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits

of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT IX
CONSTRUCTIVE FRAUD

166. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

167. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the olmesartan products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs.

168. Despite their unique knowledge regarding the defective nature of the olmesartan products, Defendants continue to suppress, conceal, omit, or misrepresent information to Plaintiffs, the medical community, or the FDA, concerning the severity of risks and the dangers inherent in the recommended and marketed use of the olmesartan products, as compared to safer alternative products. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the olmesartan products had a higher risk of adverse effects, in addition to, and exceeding alternative products in its class. Instead, Defendants have misrepresented the safety and efficacy of the olmesartan products.

169. On information and belief, Defendants' misrepresentations are or were designed to induce physicians and Plaintiffs to prescribe, dispense, recommend, or purchase the olmesartan products. Plaintiffs and the medical community have relied upon Defendants' misrepresentations.

170. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

171. As a result of Defendants' foregoing acts and omissions, Plaintiffs were or still are caused to suffer, or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life complications, potential

death, as well as the need for lifelong medical treatment, monitoring or medications, and fear of developing any of the above named health consequences.

172. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require healthcare and services, and have incurred medical, healthcare, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care, hospital care, or additional medical services.

173. As a foreseeable, direct and proximate result of Defendants' willful and wanton misconduct and reckless disregard for Plaintiffs' well-being, Plaintiffs are entitled to punitive and exemplary damages as well as compensatory damages.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT X
FRAUD

174. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

175. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and U.S. consumers, including plaintiffs and their healthcare providers, that the olmesartan products had been adequately tested in clinical trials and were found to be safe and effective as an antihypertensive treatment.

176. Defendants knew or should have known at the time they made their fraudulent misrepresentations, that their misrepresentations were false and fraudulent regarding the dangers and risk of adverse health events associated with use of the olmesartan products. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and wellbeing of the users of the olmesartan products, such as Plaintiffs.

177. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, Plaintiffs, and the public, and also inducing the medical community, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the olmesartan products, for use as an antihypertensive and for uses other than those approved and indicated in the products' label.

178. Defendants' fraudulent misrepresentations intentionally concealed the following material information:

a. The olmesartan products were not as safe and effective as other antihypertensive drugs given its intended use(s);

b. Ingestion of the olmesartan products would not result in a safe and more effective method of antihypertensive treatment than other available treatments;

c. That the risks of harm associated with the use of the olmesartan products were greater than the risks of harm associated with other forms of antihypertensive drug therapies;

d. That the risk of adverse events with the olmesartan products were not adequately tested and were known by Defendants, but Defendants knowingly failed to adequately test the products, knew that the risks of harm associated with the use of the olmesartan products were greater than the risks of harm associated with other forms of antihypertensive drug therapies, yet knowingly made material misrepresentations and omissions of fact regarding the testing data on which Plaintiffs relied in ingesting the olmesartan product(s);

e. That the limited clinical testing revealed that the olmesartan products had an unreasonably high risk of adverse effects given its intended use(s) and higher risk of adverse effects, in addition to, and above and beyond those associated with other antihypertensive drug therapies, including, *inter alia*, stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, nausea, weight loss, vomiting, malnutrition and dehydration;

f. That Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

g. Defendants were aware, and had knowledge of the dangers involved with the use of the olmesartan products, which dangers were greater than those associated with other antihypertensive drug therapies;

h. That patients using the olmesartan products could suffer intestinal damage and would require monitoring while treating with olmesartan drug therapy; and/or

i. That the olmesartan products were defective, and caused dangerous and adverse side effects, including but not limited to the specific injuries and diseases and maladies described elsewhere in this Complaint.

179. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest the olmesartan products.

180. Defendants' intentional concealment and omissions of material fact concerning the safety of the olmesartan products were made purposefully, willfully, wantonly, fraudulently, and with reckless disregard for the health and safety of Plaintiffs, with reckless intent to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the olmesartan products; and to mislead Plaintiffs into reliance upon Defendants fraudulent misrepresentations and use the olmesartan products for treatment as safe and effective antihypertensive drug therapy.

181. At the time Defendants made their misrepresentations, and at the time Plaintiffs used the olmesartan product(s), Plaintiffs were unaware of the Defendants' falsehoods, and reasonably believed them to be true.

182. Defendants knew and had reason to know that the olmesartan products could and would cause serious personal injury to the users of the product(s), and that the products were inherently dangerous in a manner that exceeded any purported inaccurate warnings given by Defendants.

183. In reliance upon Defendants' false and fraudulent misrepresentations, Plaintiffs were induced to, and did use the olmesartan product(s), thereby sustaining personal injuries and damages. Defendants knew and had reason to know that Plaintiffs and their physicians and other

healthcare providers did not have the ability to determine the true facts intentionally concealed by Defendants in prescribing and ingesting the olmesartan products, and would not have, respectively, prescribed and ingested the olmesartan products, if the true facts regarding the drugs had not been concealed by Defendants.

184. Plaintiffs reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of the olmesartan products.

185. As a result of Defendants' research and testing or lack thereof, Defendants willfully, wrongfully, and intentionally distributed false information, including but not limited to, assuring Plaintiffs, the public, and Plaintiffs' healthcare providers and physicians, that the olmesartan products were safe for use as a means of hypertensive treatment. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed from the medical community, Plaintiffs, and other consumers, the true results of Defendants clinical tests and research.

186. As a direct and proximate cause of Defendants described acts and omissions, and Plaintiffs' ingestion of Defendants' defective product, Plaintiffs have suffered serious physical injuries and have incurred substantial medical costs and expenses to treat and care for their injuries described herein. As a further direct and proximate result of Defendants acts and omissions, Plaintiffs will continue to suffer physical and emotional injuries, and will continue to incur significant medical costs and expenses, expend large sums of money to pay for medical care and treatment of their physical injuries, and will continue to suffer economic loss, and physical and emotional injuries.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT XI
CIVIL CONSPIRACY

187. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

188. Defendants, in a combination of two or more persons, acted with a common purpose to do an illegal act or to do a lawful act by unlawful means or for an unlawful purpose. Specifically, Defendants violated the United States Food, Drug and Cosmetic Drug Act, 21 U.S.C. § 321 et seq. and parallel state Food, Drug and Cosmetic Acts, and state common law by selling and distributing a drug product that was misbranded or adulterated under the federal Food, Drug and Cosmetic Act.

189. In addition, Defendants acted with a common purpose to negligently, intentionally, or fraudulently without information regarding the safety of the olmesartan products for the purpose of earning profits at the expense of Plaintiffs' health.

190. Defendants overtly acted by hiding safety information regarding the olmesartan products and failing to disclose such information to Plaintiffs, Plaintiffs' physicians, the FDA, and the medical community in pursuance of monetary benefit.

191. As a consequence of Defendants' wrongful conduct, actual legal damage has occurred to Plaintiffs and the public.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT XII
BREACH OF EXPRESS WARRANTIES

192. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

193. Defendants expressly warranted that the olmesartan products which they designed, manufactured, sold, distributed, promoted, packaged, marketed or otherwise placed in the stream of commerce, were merchantable, reasonably fit for use and safe for their intended purposes.

194. Defendants breached said warranties in that the olmesartan products were defective, dangerous, unfit for use, not merchantable and not safe for their intended, ordinary and foreseeable use and purpose.

195. Defendants placed the olmesartan products into the stream of commerce for sale and recommended its use to physicians, the FDA, and consumers without adequately warning of the risks associated with the use of the olmesartan products.

196. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale and release of the olmesartan products, including a duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side effects;

b. Warn of dangerous and potentially fatal side effects;

c. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiffs;

d. When Plaintiffs' physicians prescribed the olmesartan product(s) and Plaintiffs made the decision to use the drug, both reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers, and side effects of the olmesartan products.

197. Plaintiffs' physician(s), the FDA, or the Plaintiffs had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the olmesartan products when prescribed or otherwise provided the olmesartan product(s), and Plaintiffs purchased and used the olmesartan product(s) as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold or otherwise released into the stream of commerce by the Defendants.

198. Plaintiffs justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of the olmesartan product(s).

199. Defendants were under a duty to disclose the defective and unsafe nature of the olmesartan products to physicians, the FDA, consumers and users, such as Plaintiffs. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA, and users such as Plaintiffs, could not have reasonably discovered such defects.

200. By the conduct alleged, Defendants, their agents and employees expressly warrant to Plaintiffs and Plaintiffs' physician(s) that the products were merchantable and fit for the purpose intended.

201. This warranty was breached because the olmesartan products were not safe and effective as a medication for hypertension, as Defendants had represented and Plaintiffs were injured.

202. As a direct and proximate result of Defendants' conduct as aforesaid, Plaintiffs suffered past and future personal injuries and losses including the following:

a. past and future emotional pain and suffering;

b. past and future diminished quality of life;

c. past and future medical care and treatment and associated expenses, life care expenses, out-of-pocket expenses, and incidental expenses;

d. past and future mental anguish, humiliation, embarrassment, and loss of life's pleasures;

e. past and future physical pain and suffering, scarring, and disfigurement;

f. past and future loss of ability to perform the usual duties, vocation, and occupation, as well as other work-related benefits, and loss of profits, earnings, and earning capacity; and

g. past and future disability.

203. The injuries and losses suffered by Plaintiffs are a direct and proximate result of the negligence and carelessness of the Defendants and are not due to any act or failure to act on the part of the Plaintiffs.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits

of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT XIII
BREACH OF IMPLIED WARRANTIES

204. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

205. At all relevant times in this action, Defendants manufactured, distributed, sold, advertised, promoted, and sold the olmesartan products.

206. At all relevant times, Defendants intended that the olmesartan products be used in the manner that Plaintiffs in fact used it and Defendants impliedly warranted each product to be of merchantable quality, safe, and fit for such use, and was not adequately tested.

207. Defendants were aware that consumers, including Plaintiffs, would use the olmesartan products as marketed by Defendants, which is to say that Plaintiffs were a foreseeable user of the olmesartan products.

208. Plaintiffs were at all relevant times in privity with Defendants.

209. The drug was expected to reach and did in fact reach consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

210. Defendants breached various implied warranties with respect to the olmesartan products, including the following particulars:

a. Defendants, through advertising and promotional materials and the statements of sales representatives and paid endorsers, impliedly warranted that the olmesartan products were safe for which they were intended.

b. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the olmesartan products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury or death associated with using the olmesartan products;

c. Defendants represented that the olmesartan products were safe, or safer than other alternative medications and fraudulently concealed information, which demonstrated that the olmesartan products were not safer than alternatives available on the market; and

d. Defendants represented that the olmesartan products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy and safety of the drug.

211. In reliance upon Defendants' implied warranty, Plaintiffs used the olmesartan products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Defendants.

212. Defendants breached their implied warranty to Plaintiffs in that the olmesartan products were not of merchantable quality, safe or fit for its intended use, or adequately tested, in violation of applicable state laws.

213. Plaintiffs were or still are caused to suffer or are at a greatly increased risk of serious and dangerous side effects including, *inter alia*, severe diarrhea, weight loss, vomiting, nausea, malnutrition, dehydration, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life complications, potential death, as well as the need for lifelong medical treatment, monitoring or medications, and fear of developing any of the above named health consequences.

214. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require healthcare and services, and have incurred medical, healthcare, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care, hospital care, or additional medical services.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT XIV
PUNITIVE DAMAGES

215. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

216. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiffs, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the olmesartan products. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of the olmesartan products, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting the olmesartan products, despite Defendants' knowledge and awareness of the serious side effects and risks associated with the olmesartan products.

217. Defendants had knowledge of, and were in possession of evidence demonstrating that the olmesartan products caused serious side effects. Notwithstanding Defendants' knowledge of the serious side effects of the olmesartan products, Defendants continued to market the drug products by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the olmesartan products.

218. Although Defendants knew or recklessly disregarded the fact that the olmesartan products cause debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute the olmesartan products to consumers, including Plaintiffs, without disclosing these side effects when there were safer alternative methods for treating hypertension.

219. Defendants failed to provide warnings that would have dissuaded physicians from prescribing the olmesartan products and consumers from purchasing and ingesting the olmesartan product(s), thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the olmesartan products.

220. Defendants knew of the olmesartan products' defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs in a conscious or negligent disregard of the foreseeable harm caused by the olmesartan products.

221. The aforementioned conduct of Defendants was committed with knowing, conscious, and deliberate disregard of the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in the amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT XV
LOSS OF CONSORTIUM— CLAIMS ASSERTED BY PLAINTIFF FRANCES MARY EWALD

222. Plaintiff Frances Mary Ewald hereby incorporates by reference all previous paragraphs, as though alleged fully in this Cause of Action, and complains of Defendants and for a Fifteenth Cause of Action alleges as follows.

223. Plaintiff Frances Mary Ewald is, and at all times herein mentioned was, the lawful spouse of Plaintiff Michael Ewald.

224. As a direct, legal, and proximate result of the culpability and fault of Defendants, be such fault through strict liability or negligence, Plaintiff Frances Mary Ewald has suffered and continues to suffer the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to her general damage in an amount in excess of the jurisdictional minimum of this Court.

225. As alleged above, Defendants knew and had reason to know that Benicar posed a risk of harm to Plaintiff Michael Ewald and other consumers like him, and to Plaintiff Frances Mary Ewald, and other spouses like her.

226. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with Benicar and continuing to market, promote, sell and defend Benicar.

227. Defendants' conduct, as alleged above, was oppressive, malicious, wanton, subjected Plaintiffs and others like them to cruel and unjust hardship, and constitutes a willful, conscious and wanton disregard for the rights and safety of others. Such conduct warrants imposition of punitive damages.

RELIEF REQUESTED

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Awarding Plaintiffs compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

B. Awarding Plaintiffs punitive damages against Defendants in an amount sufficient to punish Defendants for its wrongful conduct and to deter similar wrongful conduct in the future;

C. Awarding Plaintiffs costs and disbursements, costs of investigation, attorneys' fees and all other relief available under applicable law;

D. Awarding that the costs of this action be taxed to Defendants; and

E. Awarding such other and further relief as the Court may deem just and proper.

Dated: January 12, 2015

Respectfully submitted,

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

By: */s/ Lexi J. Hazam*
Lexi J. Hazam

Robert Nelson (State Bar No. 132797)
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Lexi Hazam (State Bar No. 224457)
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ABBOTT LAW GROUP, P.A.
2929 Plummer Cove Road
Jacksonville, Florida 32223
(904) 292-1111

Attorneys for Plaintiffs

JURY DEMAND

Plaintiffs demand trial by jury on all of the triable issues in this Complaint.

Dated: January 12, 2015

Respectfully submitted,

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

By: */s/ Lexi J. Hazam*
Lexi J. Hazam

Robert Nelson (State Bar No. 132797)
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Attorneys for Plaintiffs

JS 44 (Rev. 12/12) cand rev (1/15/13)

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

Louis Verduzco and Michael Ewald

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Lexi J. Hazam
Lieff Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956.1000 Fax: (415) 956.1008

DEFENDANTS

1. Daiichi Sankyo, Inc..
2. Daiichi Sankyo US Holdings, Inc.
3. Daiichi Sankyo Co., Ltd.
4. Forest Laboratories, Inc.
5. Forest Pharmaceuticals, Inc.
6. Forest Research Institute, Inc.

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

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

Attorneys *(If Known)*
[To be added]

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product liability and negligence for injuries caused by defective drug

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ Over $75,000

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
01/12/2015

SIGNATURE OF ATTORNEY OF RECORD
Lexi Hazam

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) ☑ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA

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.