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10  
11 UNITED STATES DISTRICT COURT  
12 NORTHERN DISTRICT OF CALIFORNIA  
13

14 LOUIS VERDUZCO, MICHAEL  
15 EWALD, and FRANCES MARY EWALD

16 Plaintiffs,

17 v.

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

21 and

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

24 and

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

28 and

**CASE NO. 3:15-cv-159**

**COMPLAINT**

**DEMAND FOR JURY TRIAL**

1 FOREST LABORATORIES, INC.,  
2 and  
3 FOREST PHARMACEUTICALS, INC.,  
4 and  
5 FOREST RESEARCH INSTITUTE, INC.,  
6  
7 Defendants.

8  
9 **COMPLAINT**

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

13 **INTRODUCTION**

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

20 **PARTIES**

21 **Plaintiffs**

- 22 1. Plaintiffs Louis Verduzco is a resident of Oakland, California.  
23 2. Michael Ewald and Frances Mary Ewald are residents of Bakersfield, California.  
24 3. Plaintiffs claim and allege that their damages and injuries are the direct and  
25 proximate result of Defendants’ negligent, intentional, and wrongful acts, omissions, and conduct  
26 regarding Defendants’ design, development, formulation, manufacture, testing, packaging,  
27 labeling, promotion, advertising, marketing, distribution and sale of products containing the drug  
28 *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.

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

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

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

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

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

25           17.     For convenience purposes, Daiichi Sankyo Japan, Daiichi Sankyo U.S., and  
26 Daiichi Sankyo U.S. Holdings, Inc., are hereinafter collectively referred to as “Daiichi Sankyo.”  
27  
28

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

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

9           **B.     Forest Defendants**

10          20.     On information and belief, Forest Laboratories, Inc. (“Forest Labs”) is a Delaware  
11     corporation having a principal place of business at 909 Third Avenue, New York, New York  
12     10022. Forest Labs is in the business of manufacturing, distributing, marketing or promoting  
13     numerous pharmaceutical drugs for sale and use throughout the United States, including within  
14     the State of California.

15          21.     On information and belief, Forest Pharmaceuticals, Inc. (“Forest  
16     Pharmaceuticals”) is incorporated in Delaware with its principle place of business located at  
17     13600 Shoreline Drive, St. Louis, Missouri. At all times relevant to this action, Defendant Forest  
18     Pharmaceuticals is and has been a division and wholly owned subsidiary of Forest Labs  
19     responsible for the manufacture, distribution, and sales of prescription medicine for Forest Labs.  
20     Forest Pharmaceuticals has at least eight offices in New York and regularly transacts business  
21     within the State of California.

22          22.     On information and belief, Forest Research Institute, Inc. (“FRI”), is a wholly-  
23     owned subsidiary of Forest Laboratories, Inc., and was and still is a corporation duly existing  
24     under and virtue of the laws of the State of New Jersey with its principal place of business at  
25     Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times  
26     hereinafter mentioned, Defendant FRI was and still is a pharmaceutical entity involved in  
27     research, development, testing, manufacture, production, promotion, distribution and marketing  
28

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

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

12 24. For convenience purposes, Defendants Forest Labs, Forest Pharmaceuticals and  
13 FRI are hereinafter referred collectively as “Forest.”

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

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

20 **C. All Defendants**

21 27. The term “Defendants” is used hereafter to refer to all the entities named above.

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

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

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

### 7 **JURISDICTION AND VENUE**

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

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

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

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

23 34. At all times relevant to this action, the Defendants have been engaged either  
24 directly or indirectly in the business of distributing prescription drug products, including the  
25 *olmesartan medoxomil* products, within the State of California, with a reasonable expectation that  
26 the products would be used or consumed in this state, and thus have regularly solicited or  
27 transacted business in this state.  
28

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

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

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

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

23           39.     This court has personal jurisdiction over Forest Pharmaceuticals based on its  
24 contacts within the State of California relating to the subject matter of this action and because  
25 Forest Pharmaceuticals has continuous and systematic contacts with this judicial district. Among  
26 other things, Forest Pharmaceuticals entered co-marketing agreements with Daiichi Sankyo  
27 relating the *olmesartan* products in this action.  
28





1 United States Food and Drug Administration (“FDA”) on April 25, 2002, for treatment of  
2 hypertension.

3 48. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 21-  
4 532 for Benicar HCT® tablets (40/12.5 mg, 40/25 mg, and 20/12.5 mg), which tablets contain the  
5 active ingredients *olmesartan medoxomil* and *hydrochlorothiazide*. Benicar HCT® tablets were  
6 approved by the FDA on June 5, 2003, for the treatment of hypertension, but are not indicated for  
7 initial therapy.

8 49. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 22-  
9 100 for Azor® tablets (5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg), which tablets contain the  
10 active ingredients *amlodipine besylate* and *olmesartan medoxomil*. Azor® tablets were approved  
11 by the FDA on September 26, 2007 for the treatment of hypertension, alone or in combination  
12 with other antihypertensive agents.

13 50. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 20-  
14 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  
15 mg), which tablets contain the active ingredients *olmesartan medoxomil*, *amlodipine* and  
16 *hydrochlorothiazide*. Tribenzor® tablets were approved by the FDA on July 23, 2010, for  
17 treatment of hypertension, but are not indicated for initial therapy.

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

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

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

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

1 pharmacies, or from which “product samples,” if any, were to be dispensed by doctors. The  
 2 labeling includes information on the product’s active and inactive ingredients, clinical  
 3 pharmacology, “indications” and usage, contraindications, warnings, precautions, and side effects  
 4 (adverse reactions and overdose).

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

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

10 57. The package inserts for the olmesartan products are materially identical to the  
 11 “monograph” for the olmesartan products published in the Physician’s Desk Reference.

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

13 **FDA Drug Safety Communication and Label Change**

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

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

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

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

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

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

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

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

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

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

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

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

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

26 a. Studies published in peer-reviewed scientific and medical literature found  
27 there may be an association between olmesartan and sprue-like enteropathy;  
28

- 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.

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

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

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

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

16           **Efficacy of Olmesartan Products**

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

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

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

26           **Plaintiffs' Ingestion of the Olmesartan Product(s)**

27           79.     Plaintiffs were prescribed Benicar® by their treating physicians.  
28

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

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

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

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

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

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

23          86.     Plaintiffs Louis Verduzco and Michael Ewald have suffered unavoidable, serious  
24 and life threatening physical injuries, severe emotional distress, and mental injuries in coping  
25 with their physical injuries, and have incurred and expended significant amounts for the medical  
26 care, hospitalizations, and medications, required to treat and care for olmesartan-related disease,  
27 pain, and suffering and will continue to do so long into the future.  
28



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.

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

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

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

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

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

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

26                 c.     The drug was insufficiently tested;

27                 d.     The drug caused harmful side effects that outweighed any potential utility;  
28

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

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

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

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

13 i. Inadequate post-marketing surveillance; and/or

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

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

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

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

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

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

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

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

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

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

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

25 **COUNT II**  
26 **PRODUCTS LIABILITY – FAILURE TO WARN**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named  
27 Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits  
28 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;

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

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

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

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

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

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

25          WHEREFORE, Plaintiffs demands judgment in their favor and against the above-named  
26      Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits  
27      of this Court, together with all lawful fees, costs and such other relief as this Court deems just and  
28      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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 150. Defendants failed to comply with the FDA postmarketing reporting requirements  
 20 under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse drug experience  
 21 concerning the olmesartan products that is both serious and unexpected, whether foreign or  
 22 domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the  
 23 information by Defendants, failing to promptly investigate all adverse drug experiences  
 24 concerning the olmesartan products that are the subject of these postmarketing 15-day Alert  
 25 reports, failing to submit follow up reports within 15 calendar days of receipt of new information  
 26 or as requested by the FDA, and, if additional information is not obtainable, failing to maintain  
 27 records of the unsuccessful steps taken to seek additional information. Defendants' failure to  
 28 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

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

4 **COUNT VII**  
5 **NEGLIGENT MISREPRESENTATION**

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

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

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

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

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

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



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

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

8 **COUNT VIII**  
 9 **FRAUDULENT CONCEALMENT**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 **COUNT IX**  
4 **CONSTRUCTIVE FRAUD**

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

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

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

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

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

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

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

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

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

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

15 **COUNT X**  
16 **FRAUD**

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

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

23 176. Defendants knew or should have known at the time they made their fraudulent  
24 misrepresentations, that their misrepresentations were false and fraudulent regarding the dangers  
25 and risk of adverse health events associated with use of the olmesartan products. Defendants  
26 made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and  
27 depraved indifference for the safety and wellbeing of the users of the olmesartan products, such  
28 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;

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

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

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

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

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

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

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

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

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

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

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

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

23 WHEREFORE, Plaintiffs demand judgment in their favor and against the above named  
24 Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits  
25 of this Court, together with all lawful fees, costs and such other relief as this Court deems just and  
26 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.



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

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

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

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

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

15               b. Warn of dangerous and potentially fatal side effects;

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

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

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

27           198. Plaintiffs justifiably and detrimentally relied on the warranties and representations  
28 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

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

3 **COUNT XIII**  
4 **BREACH OF IMPLIED WARRANTIES**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 WHEREFORE, Plaintiffs demand judgment in their favor and against the above-named  
25 Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits  
26 of this Court, together with all lawful fees, costs and such other relief as this Court deems just and  
27 proper.  
28

**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.



1 Dated: January 12, 2015

Respectfully submitted,

2 LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

3  
4 By: /s/ Lexi J. Hazam

5 Lexi J. Hazam

6 Robert Nelson (State Bar No. 132797)

7 [rnelson@lchb.com](mailto:rnelson@lchb.com)

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13 Jacksonville, Florida 32223

14 (904) 292-1111

15 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

## 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  
Lief 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
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question  
(U.S. Government Not a Party)
- ☒ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

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

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**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

K00FKKIQPCN'CUH PO GPV'EklN0105/4+

(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.