UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

KALAWATTI KAY SCHEFFLER
AND JAMES E. SCHEFFLER,

Plaintiffs,

vs.

DAIICHI SANKYO, INC., d/b/a Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma, Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research Institute, Inc., Daiichi Pharma Holdings, Inc.,

And

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

And

FOREST LABORATORIES, LLC, f/k/a Forest Laboratories, Inc.,

And

FOREST PHARMACEUTICALS, INC.,

And

FOREST RESEARCH INSTITUTE, INC.,

Defendants.

Case No.:_____

COMPLAINT
AND
DEMAND FOR JURY TRIAL

Plaintiffs, Kalawatti Kay Scheffler and James E. Scheffler, for their causes of action against the above-named Defendants, allege and state on information and belief as follows:

INTRODUCTION

Plaintiffs Kalawatti Kay Scheffler and James E. Scheffler, husband and wife, bring this action for personal injuries suffered by Plaintiff Kalawatti Kay Scheffler, as well as the loss of consortium claims of Plaintiff James E. Scheffler as a proximate result of Benicar® being prescribed and ingesting the defective and unreasonably dangerous pharmaceutical blood pressure medication containing the drug olmesartan medoxomil, which is and was at all times relevant to this action, manufactured, designed, researched, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein. Plaintiff(s) allege(s) as follows:

PARTIES

Plaintiffs

1. Plaintiff Kalawatti Kay Scheffler is an adult individual is and was, at all times relevant to this action, a citizen and resident of the city of Des Moines, county of Polk, State of Iowa. Plaintiff brings this action against Defendants for the personal injuries she suffered as a result of ingesting the pharmaceutical drug containing olmesartan medoxomil, which Plaintiff believes and alleges is and was designed, compounded, manufactured, researched, tested, marketed, advertised, labeled, distributed, sold, packaged or promoted by the Defendants identified in this Complaint.

2. Plaintiff Kalawatti Kay Scheffler is an adult individual and resides with her spouse, James E. Scheffler. At all times relevant to this action, Plaintiffs were legally married as husband and wife. James E. Scheffler brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his spouse, Kalawatti Kay Scheffler.

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

Defendants

A. Daiichi Sankyo Defendants

4. On information and belief, Defendant Daiichi Sankyo, Inc. 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, Inc. 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, Inc. 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 Iowa.

7. On information and belief, Daiichi Sankyo, Inc. 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, Inc. 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. There existed, at all relevant times to this action, a unity of interest in ownership between Daiichi Sankyo, Inc., and Daiichi Sankyo U.S. Holdings, Inc., such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these two Defendants, and each of them are the alter egos of one another and exerted direct control over each other. Adherence to the fiction of a separate and independent existence among the two Defendants, as separate entities distinct from one another will permit an abuse of the corporate privilege, sanction a fraud upon the plaintiff and other consumers of their products containing olmesartan medoxomil, and promote injustice. The two Defendants, and each of them,

condoned and ratified the negligent, willful, intentional, and wrong acts, omissions, and conduct of each other.

12. For convenience purposes Daiichi Sankyo, Inc., and Daiichi Sankyo U.S. Holdings, Inc., are hereinafter collectively referred to as "Daiichi Sankyo."

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

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

B. Forest Defendants

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

16. On information and belief, Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") is incorporated in Delaware with its principle place of business located at 13600 Shoreline Drive, St. Louis, Missouri. At all times relevant to this action,

Defendant Forest Pharmaceuticals is and has been a division and wholly owned subsidiary of Forest Labs responsible for the manufacture, distribution, and sales of prescription medicine for Forest Labs.

17. On information and belief, Forest Research Institute, Inc. ("FRI"), is a wholly-owned subsidiary of Forest Laboratories, Inc., and is incorporated in New Jersey with its principal place of business at Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times hereinafter mentioned, Defendant FRI was and still is a pharmaceutical entity involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of drug medicine, throughout the United States.

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

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

20. On information and belief, Defendants Forest and Daiichi Sankyo entered an expense and profit sharing relationship in exchange for the co-promotion of blood pressure drugs containing olmesartan medoxomil, including but not limited to Benicar®, Benicar HCT®, Azor®, and Tribenzor® (hereinafter collectively referred to as the "olmesartan products").

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

C. All Defendants

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

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

24. At all times relevant to this action, all Defendants and each of them were in the capacity of the principal or agent of all of the other Defendants, and each of them, and acted within the scope of their principal and agent relationships in undertaking their actions, conduct, and omissions alleged in this Complaint. All Defendants, and each of them, acted together in concert or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of reaping

substantial monetary profits from the sale of the olmesartan products and for the purpose of enriching themselves financially to the serious detriment of Plaintiffs' health and well being.

JURISDICTION AND VENUE

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

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

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

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

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

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

31. Defendant Daiichi Sankyo, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and New Jersey.

32. Defendant Daiichi Sankyo U.S. Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and New Jersey.

33. Defendant Forest Labs is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New York. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and New York.

34. Defendant Forest Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Missouri. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and Missouri.

35. Defendant FRI is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, it is a citizen of New Jersey.

36. This action is properly before the Court because there is complete diversity of citizenship between plaintiff and defendants. In addition, the amount in controversy claimed by plaintiff exceeds $75,000. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

37. Venue is proper within this District pursuant to 28 U.S.C. § 1391 Defendants are subject to personal jurisdiction within this District in accordance with 28 U.S.C. §1391(c), in that Defendants did and do business within and have continuous and systematic contacts with the state of Iowa, have consented to jurisdiction in the state of Iowa and/or committed a tort in whole or in part in the state of Iowa against Plaintiff, as more fully set forth herein. On information and belief, defendants also advertised in this district, and made material omissions and representations in this district.

FACTUAL BACKGROUND

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

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

40. On information and belief, olmesartan medoxomil is classified as an angiotension II receptor blocker ("ARB"). At all times relevant to this action, there were seven commercialized ARB monotherapy products available. Olmesartan medoxomil was the seventh and last to the ARB market.

41. On information and belief, Daiichi Sankyo, Inc., f/k/a Sankyo Pharma, holds an approved new drug application ("NDA'') No. 21-286 for Benicar® tablets (5 mg, 20 mg, and 40 mg), which tablets contain the active ingredient olmesartan medoxomil. Benicar® tablets were approved by the United Stated Food and Drug Administration ("FDA") on April 25, 2002, for treatment of hypertension.

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

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

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

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

46. On information and belief, Daiichi Sankyo refers to its olmesartan medoxomil products as the "Benicar Family."

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

48. As required by law for all prescription drug products, each of the Defendants include the product's "labeling," as approved by the FDA, on labels, also called "package inserts," placed on or in the packages from which the products were to be dispensed from pharmacies, or from which "product samples," if any, were to be dispensed by doctors. The labeling includes information on the product's active and inactive ingredients, clinical pharmacology, "indications" and usage, contraindications, warnings, precautions, and side effects (adverse reactions and overdosage).

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

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

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

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

FDA Drug Safety Communication and Label Change

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

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

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

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

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

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

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

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

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

i. In May 2013, an article describing patients with villous atrophy and negative serologies for celiac disease reported that some patients without definitive etiologies were characterized as having unclassified sprue.

Some of these patients were subsequently found to have villous atrophy associated with olmesartan use.

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

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

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

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

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

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

d. Clinical trials for the olmesartan drug only 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.

55. Numerous additional case reports and articles have been published in the past few years documenting intestinal injury to users of olmesartan products, including but not limited to:

a. S.E. Dreifuss, Y. Tomizawa, N.J. Farber, et al., *Spruelike Enteropathy Associated with Olmesartan: An Unusual Case of Severe Diarrhea*. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 20 February 2013.

b. M. DeGaetani, C.A. Tennyson, et al. *Villous Atrophy and Negative Celiac Serology: A Diagnostic and Therapeutic Dilemma*. Am. J. Gastroenterol. 2013 May; 108(5): 647-53.

c. J.A. Nielsen, A. Steephen, M. Lewin. *Angiotensin-II inhibitor (olmesartan)-induced collagenous sprue with resolution following discontinuation of drug*. World J. Gastroenterol. 2013 Oct 28; 19(40): 6928-30 .

d. P.P. Stanich, M. Yearsley, M.M. Meyer. *Olmesartan-associated Sprue-like Enteropathy*. J. Clin. Gastroenterol. 2013 Nov/Dec; 47(10): 894-5.

e. H. Theophile, X.R. David, et al. *Five cases of sprue-like enteropathy in patients treated by olmesartan*. Dig. Liver Dis. 2014 Jan 25. Epub ahead of print.

f. M. Abdelghany, L. Gonzalez, et al. *Olmesartan Associated Sprue-like Enteropathy and Colon Perforation*. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 29 January 2014

g. G. Ianiro, S. Bibb, et al. *Systematic Review: Sprue-Like Enteropathy Associated with Olmesartan*. Ailment. Pharmacol. Ther. 2014; 40: 16-23.

h. M.L. Sanford and A.K. Nagel, *A Review of Current Evidence of Olmesartan Medoxomil Mimicking Symptoms of Celiac Disease.* J. Pharm. Prac. 1-4 (2014).

i. M. Basson, M. Mezzarobba, et al. *Severe Malabsorption Associated with Olmesartan: A French Nationwide Cohort Study.* (Abstract only.)

j. T.H. Tran and H. Li, *Olmesartan and Drug-Induced Enteropathy*. Pharmacovig. Forum, Vol. 39 No. 1 (Jan. 2014).

k. L. Marthey, G. Cadiot, et al. *Olmesartan-associated Enteropathy: Results of a National Survey.* Ailment. Pharmacol. Ther. (Aug. 2014).

FDA Investigates Risk of Cardiovascular Events

56. In 2010, the FDA issued a Drug Safety Communication announcing that the agency was 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®.

57. 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. 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.

Defendants' False and Misleading Advertising which Omitted and/or Minimized Information about Risks Associated with Olmesartan

58. On information and belief, Daiichi Sankyo paid Forest millions of dollars between 2002 and 2008 to promote Benicar® and Benicar HCT®.

59. 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.

60. The U.S. market for hypertension treatment is massive. Approximately 73 million people in the United States age 20 and older have hypertension, about 70 percent of adults with hypertension use medication to treat the condition.

61. On information and belief, Daiichi Sankyo invested heavily in marketing directly to physicians to promote its olmesartan products.

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

63. 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.

64. 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, thereby misleadingly signaling to the reader that the risks that were presented were minimal.

65. The FDA ordered Daiichi Sankyo and Forest to cease making these superiority and efficacy claims and to take corrective measures. The corrective measures included discontinuing use of approximately fifty promotional pieces dated

all the way to 2002 and dissemination of corrective messages to physicians who received the materials.

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

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

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

Efficacy of Olmesartan Products

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

Plaintiffs Ingestion of the Olmesartan Product(s)

70. In approximately January of 2011, Plaintiff Kalawatti Kay Scheffler was prescribed

Azor®, and ingested and used Azor® according to its intended and directed use.

71. While taking the recommended dosage of Azor®, Plaintiff suffered bodily injury including sprue-like enteropathy (specifically diagnosed at the Mayo Clinic in Rochester Minnesota, from small bowel biopsies, as "villous atrophy with intraepithelial lymphocytosis"), with severe, chronic diarrhea resulting in substantial weight loss and malnutrition and was thus caused to sustain severe and permanent personal injuries, pain, and suffering while still actively taking Azor®.

72. It was and is necessary for Plaintiff's medical conditions to be monitored by physicians and other health care providers to determine sequelae associated with intestinal and/or colonic disease manifestations, as well as severe chronic diarrhea, rapid and substantial weight loss, severe malnutrition, and severe dehydration.

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

74. Plaintiff has suffered unavoidable, serious and life threatening physical injuries, severe emotional distress, and mental injuries in coping with his physical injuries, and has incurred and expended significant amounts for the medical care, hospitalizations, and medications, required to treat and care for her olmesartan-related disease, pain, and suffering and will continue to do so long into the future.

COUNT I
PRODUCTS LIABILITY- DEFECTIVE DESIGN

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

76. Defendants have a duty to provide adequate warnings and instructions for the olmesartan product (s), to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately test its product.

77. At all times relevant to this action, the Defendants researched, designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold the olmesartan product(s), placing the drug into the stream of commerce.

78. At all times relevant to this action, the olmesartan product(s), was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition that was defective and unreasonably dangerous to consumers, including the Plaintiffs.

79. The olmesartan product ingested by Plaintiff, is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

80. The olmesartan product ingested by Plaintiff, as manufactured and supplied, was defective due to, *inter alia*:

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

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

c. The drug was insufficiently tested;

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

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

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

g. Defendants were aware at the time the olmesartan products were marketed that chronic, long-term intake of the olmesartan products would result in an increased risk of gastrointestinal injury, sprue-like

enteropathy, chronic diarrhea, weight loss, hospitalization(s) related to dehydration and malnutrition, vomiting, and/or severe nausea;

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

i. There was inadequate post-marketing surveillance; and/or

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

81. The olmesartan product(s), was expected to reach, and did reach, users and/or consumers, including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

82. Plaintiffs used the olmesartan product(s), as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

83. The olmesartan product(s) was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiffs, including when it was used as intended and in a reasonably foreseeable manner.

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

85. The olmesartan product(s) was unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of serious gastrointestinal injury, including sprue-like enteropathy and/or chronic and severe diarrhea, and other serious

injury, which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative methods and designs for the like product.

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

87. As a direct and proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Defendants' defective product, Plaintiff has suffered serious physical injuries and has incurred substantial medical costs and expenses to treat and care for her injuries described herein, in addition, she has suffered physical pain and mental anguish, diminished physical abilities and ability to engage in daily activities, and will continue to suffer economic loss, and physical and emotional injuries in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II
PRODUCTS LIABILITY- FAILURE TO WARN

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

89. The olmesartan product ingested by Plaintiff was defective and unreasonably dangerous when it left the possession of Defendants in that it contained

warnings insufficient to alert consumers, including the Plaintiff herein, to the dangerous risks and reactions associated with the drug, including severe gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, nausea, malnutrition, dehydration, and/or weight loss.

90. The Plaintiff was administered the olmesartan product(s) for its intended purpose.

91. Neither Plaintiff, nor Plaintiff's physician, knew, nor could they have learned through the exercise of reasonable care, of the risk of severe gastrointestinal injury associated with or caused by the olmesartan product.

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

93. Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the olmesartan products.

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

95. The dangerous propensities of the olmesartan products, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied or sold

the product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

96. Each of the Defendants knew or should have known that the limited warnings disseminated with the olmesartan products were inadequate.

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

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

99. As a direct and proximate result of the Defendants' failure to provide adequate warnings about the dangers associated with the drug, the Plaintiff has suffered and permanent physical injuries, emotional distress, economic losses and other damages to be proved at trial.

100. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and Plaintiff's healthcare provider about the increased risks of serious injury caused by olmesartan.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III
GROSS NEGLIGENCE

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

102. Defendants had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of the olmesartan product(s), including a duty to ensure that it did not cause users to suffer from unreasonable and dangerous side effects.

103. Defendants failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' product, olmesartan, in that Defendants knew or should have known that taking the olmesartan product(s), caused unreasonable and life-threatening injuries, as alleged herein.

104. Defendants were grossly negligent under the circumstances and breached their duty of care in numerous ways, including the following:

a. failing to test the olmesartan products properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of the olmesartan products;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of the olmesartan products which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of the olmesartan products;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling the olmesartan products to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the olmesartan products and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting the olmesartan products;

h. recklessly continuing to manufacture, market, advertise, and distribute the olmesartan products after Defendants knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of the olmesartan products;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of the olmesartan products, while Defendants knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of the olmesartan products for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendants to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately, and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, their doctors, other consumers, the medical community, and the FDA;

n. failing to accompany the olmesartan products with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of the olmesartan products to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to use due care in the selling of the olmesartan products to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of the olmesartan products;

u. failing to educate healthcare providers and the public about the safest use of the drug;

v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

w. being otherwise grossly negligent.

105. Although Defendants knew, or recklessly disregarded, the fact that Defendants' olmesartan products caused potentially severe gastrointestinal side effects, Defendants continued to market the olmesartan products to consumers, including Plaintiff, without disclosing these side effects.

106. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

107. Defendants knew of, or recklessly disregarded the defective nature of Defendants' olmesartan products as set forth herein, but continued to design, manufacture, market, and sell Defendants' olmesartan products, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Defendants' olmesartan products.

108. As a direct and proximate consequence of Defendants' gross negligence, the Plaintiff sustained injuries and damages alleged herein including severe physical gastrointestinal injuries, severe emotional distress, economic losses and other damages to be proved at trial.

109. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their gross negligence.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV
NEGLIGENCE

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

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

112. 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, label, promote and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

113. 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 Plaintiff.

114. 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 severe gastrointestinal injury, sprue-like enteropathy, chronic severe diarrhea, nausea, vomiting, dehydration, malnutrition and other serious injury, and thus created a dangerous and unreasonable risk of injury to users of the products.

115. 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.

116. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, testing, quality assurance, quality control, sale, and distribution of the olmesartan products in interstate commerce, in that Defendants knew and had reason to know that a consumer patient's use and ingestion of the product(s) created a significant risk of suffering unreasonably dangerous health related side effects, severe gastrointestinal injury, sprue-like enteropathy, chronic severe diarrhea, nausea, vomiting, dehydration, malnutrition and other serious injury.

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

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

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

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

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

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

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

e. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew or had reason to know that the olmesartan products were indeed unreasonably unsafe and unfit for use by reason of the product's defect

and risk of harm to its users in the form of intestinal damage and other serious illnesses;

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

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

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

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

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

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

l. Failing to disclose to Plaintiff and Plaintiff's prescribing physician(s), through the prescribing information for the olmesartan products, about the risk of developing severe gastrointestinal injury such as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and/or dehydration;

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

n. Failing to reference the chronic nature and severity of the adverse reactions provided in its label, including developing severe gastrointestinal injury such as sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration;

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

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

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

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

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

t. Failing to ensure the products were accompanied by proper and accurate warnings about the possible adverse side effects associated with the use of the olmesartan products and that such use created a risk of developing severe gastrointestinal injury such as, sprue-like enteropathy and/or lymphocytic colitis, microscopic colitis, collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, that could be life-threatening; and/or

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

120. Defendants knew or should have known that it was foreseeable that consumers such as plaintiff would suffer injuries as a result of Defendants' failure to

exercise ordinary care in the manufacturer, marketing, labeling, distribution and sale of the olmesartan products.

121. Plaintiff did not know the nature and extent of the injuries that would result from ingestion and use of the olmesartan product(s).

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

123. As a result of Defendants' acts and omissions described in this Complaint, Plaintiff was proximately caused to suffer the serious and dangerous side effects of the olmesartan products, including but not limited to severe gastrointestinal injury such as sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, dehydration and malnutrition. Plaintiff also suffered as a result of Defendants' acts and omissions, physical pain and mental anguish, significantly diminished physical abilities and the need for future medical monitoring and treatment of injuries related to Plaintiffs' ingestion of the olmesartan product(s) and the resulting medical conditions and injury.

124. As a proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Defendants' defective product, Plaintiff has suffered serious physical injuries and has incurred substantial medical costs and expenses to treat and care for the injuries described herein. As a further direct and proximate result of Defendants' acts and omissions, Plaintiff has suffered serious and physical and emotional injuries and economic loses, and will continue to suffer economic loss and physical and emotional injuries in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V
NEGLIGENCE *PER SE*

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

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

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

these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

128. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons protected by the above-mentioned statute, suffered, and will continue to suffer, injuries and is entitled to compensatory damages, and exemplary and punitive damages together with interest, and the cost of suit and attorneys' fees, in an amount to be proved at trial.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI
FRAUDULENT CONCEALMENT

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

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

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

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

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

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

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

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

134. The facts concealed or not disclosed by Defendants were not reasonably ascertainably by Plaintiff or Plaintiff's physician.

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

136. As a direct and proximate result of Defendants' foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including,

inter alia, severe gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and/or other severe and personal injuries.

137. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has incurred in the past and will incur in the future, health care, incidental, and related expenses.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VII
CONSTRUCTIVE FRAUD

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

139. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the olmesartan products, which knowledge is not possessed by Plaintiff or Plaintiff's physicians.

140. Despite their unique knowledge regarding the defective nature of the olmesartan products, Defendants suppressed, concealed, omitted, or misrepresented information to Plaintiff, the medical community, or the FDA, concerning the severity of risks and the dangers inherent in the recommended and marketed use of the olmesartan products, as compared to safer alternative products.

141. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the olmesartan products carried a risk of severe gastrointestinal injury and/or sprue-like enteropathy, which other products in their class do not have. Instead, Defendants have misrepresented the safety and efficacy of the olmesartan products, in order to convince consumers and physicians to use their olmesartan products.

142. Plaintiff and the medical community reasonably relied upon Defendants' misrepresentations.

143. As a direct and proximate result of Defendants' foregoing acts and omissions, Plaintiff sustained serious injury, including severe gastrointestinal injury, sprue-like enteropathy, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, and/or other severe and personal injuries, physical pain and mental anguish.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VIII
VIOLATION OF IOWA'S CONSUMER PROTECTION LAWS

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

145. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of olmesartan products to Plaintiff.

146. Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of Iowa's consumer protection laws, Iowa Stat. § 714h; *et seq*.

147. Through their false, untrue and misleading promotion of olmesartan products, Defendants induced Plaintiff to purchase and/or pay for the purchase of olmesartan products.

148. Defendants misrepresented the alleged benefits and characteristics of olmesartan products; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of olmesartan products; misrepresented the quality and efficacy of olmesartan products as compared to other alternatives; misrepresented and advertised that olmesartan products was of a particular standard, quality, or grade that it was not; misrepresented olmesartan products in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have switched from olmesartan products to another antihypertension medication and/or chosen not to purchase and/or reimburse for purchases of olmesartan products; advertised olmesartan products with the intent not to sell them as advertised; and otherwise engaged in fraudulent and deceptive conduct.

149. Defendants' conduct misled, deceived and damaged Plaintiff, and Defendants' fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff's rely on said conduct by purchasing and/or paying for purchases

of olmesartan products. Moreover, Defendants knowingly took advantage of Plaintiff, who was reasonably unable to protect their interests due to ignorance of the harmful adverse effects of olmesartan products.

150. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable and substantially injurious to Plaintiff and offends the public conscience.

151. Plaintiff purchased olmesartan products primarily for personal, family, or household purposes.

152. As a result of Defendant's violative conduct, Plaintiff purchased and/or paid for purchases of olmesartan products that were not made for resale.

153. Defendant engaged in unfair competition or deceptive acts or practices in violation of Iowa Stat. §714h, *et seq*.

154. As a proximate result of Defendants' misrepresentations and omissions, Plaintiff has suffered ascertainable losses, in an amount to be determined at trial.

155. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of their violations Iowa Stat. § 714h, *et seq*. prohibiting consumer fraud and deceptive and unfair trade practices

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IX
UNJUST ENRICHMENT

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

157. At all times relevant to this action, Defendants were the manufacturers, sellers, distributors, or promoters of the olmesartan products.

158. Plaintiff purchased the olmesartan product(s) for the purpose of treating hypertension in reliance upon the Defendants' representations of the safety and efficacy of the product.

159. Defendants have accepted payments from Plaintiff and other consumers for the purchase of the olmesartan product(s).

160. Plaintiff did not receive the safe and effective antihypertensive drug for which Plaintiff paid, and equity demands that Defendants be disgorged of their profits received from the defective drug and their own deception regarding the safety and efficacy of the drug.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT X
LOSS OF CONSORTIUM

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

162. At all times relevant hereto James E. Scheffler has suffered injuries and losses as a result of Plaintiff's injuries.

163. For the reasons set forth herein, James E. Scheffler have necessarily paid and have become liable to pay for medical aid, treatment, and medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of the Defendants' misconduct.

164. For the reasons set forth herein, James E. Scheffler has suffered and will continue to suffer the loss of his spouse's support, companionship, services, society, love, affection, and consortium.

165. As a direct and proximate result of the Defendant's misconduct, James E. Scheffler has sustained injuries and damages alleged herein and other damages to be proved at trial.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

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

B. Awarding Plaintiffs treble damages against Defendants so to fairly and completely compensate Plaintiffs for all damages, and to deter similar wrongful conduct in the future;

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

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

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

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

JURY DEMAND

The Plaintiffs hereby request a trial by jury, pursuant to Rule 38 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Respectfully Submitted by Attorneys:

/s _Larry D. Helvey

LARRY HELVEY LAW FIRM
Larry D. Helvey, M.D., J.D. (AT0003424)
2735 First Avenue SE, Suite 101
Cedar Rapids, IA 52402
Ph: 319-362-0421
Fax: 319-362-3496
Email: lhelvey@helveylaw.com

PEARSON, RANDALL & SCHUMACHER, PA

Vincent J. Moccio, Esq. (MN # 0184640)
100 South Fifth Street, Ste. 1025
Minneapolis, MN 55402
Ph: 612-767-7500
Fax: 612-767-7501
Email: vjmoccio@prslegal.com

JS 44 (Rev. 12/12)

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

KALAWATTI KAY SCHEFFLER AND JAMES E. SCHEFFLER

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
LARRY HELVEY LAW FIRM
2735 1ST AVENUE SE, SUITE 101
CEDAR RAPIDS, IA 52402

DEFENDANTS

DAIICHI SANKYO, INC., DAIICHI SANKYO US HOLDINGS,INC FOREST LABORATORIES, LLC, FOREST PHARMACEUTICALS, INC, 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)*

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

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

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

(For Diversity Cases Only)

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/03/2014

SIGNATURE OF ATTORNEY OF RECORD
/s/Larry D. Helvey, MD, JD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. Nature of Suit. Place an "X" in the appropriate box. If 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.