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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

WILLIAM PIERCE, an Individual; and SHARON PIERCE, an Individual,

Plaintiffs,

v.

TAKEDA PHARMACEUTICALS AMERICA, INC.;

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.;

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.;

TAKEDA PHARMACEUTICAL COMPANY LIMITED;

TAKEDA PHARMACEUTICALS, LLC;

TAKEDA PHARMACEUTICALS, LLC.;

TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.;

TAKEDA CALIFORNIA, INC., fka TAKEDA SAN DIEGO, INC.;

ELI LILLY AND COMPANY; and

DOES 1 through 100, inclusive,

Defendant.

CASE NO.

COMPLAINT FOR DAMAGES, RESTITUTION AND INJUNCTIVE RELIEF; DEMAND FOR JURY TRIAL

1. **NEGLIGENCE**
2. **STRICT LIABILITY–FAILURE TO WARN**
3. **STRICT LIABILITY– DEFECTIVE DESIGN**
4. **BREACH OF EXPRESS WARRANTY**
5. **BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE**
6. **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
7. **VIOLATION OF *CAL. BUS. & PROF. CODE*, §17200, *et seq.***
8. **VIOLATION OF *CAL. BUS. & PROF. CODE*, §17500, *et seq.***
9. **DECEIT BY CONCEALMENT**
10. **NEGLIGENT AND INTENTIONAL MISREPRESENTATION**
11. **VIOLATION OF *CAL. CIVIL CODE* § 1750, *et seq.* (CLRA)**
12. **VIOLATION OF KENTUCKY'S CONSUMER PROTECTION STATUTE**
13. **LOSS OF CONSORTIUM**

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiffs WILLIAM PIERCE, an individual; and SHARON PIERCE, an individual, for causes of action against Defendants and DOES 1 through 100, and each of them, inclusive, who file this Complaint and allege as follows:

GENERAL ALLEGATIONS

1. The Plaintiffs herein, competent individuals over the age of 18, residents and citizens of the United States, hereby submit to the jurisdiction of this Court and allege that Venue in this Court is proper.

2. Plaintiffs are residents and citizens of the State of Kentucky and currently reside in Harrodsburg, Kentucky.

3. This is an action for personal injury on behalf of the Plaintiff WILLIAM PIERCE and loss of consortium on behalf of a spouse, Plaintiff SHARON PIERCE, against Defendants and DOES 1 through 100, and each of them, inclusive, who are responsible for the prescription drug Actos and pioglitazone hydrochloride, a diabetes medication used by Plaintiff WILLIAM PIERCE that caused Plaintiff WILLIAM PIERCE to suffer physical injuries and damages including, but not limited to, bladder cancer and related sequelae, pain and suffering, bodily impairment, mental anguish, diminished enjoyment of life as well as economic loss and other special damages.

4. At all relevant times alleged herein, one or more of the corporate Defendants was, and now is, a corporation with its principal place of business in the State of California.

5. At all relevant times alleged herein, one or more of the individual Defendants was, and now is a resident of the State of California.

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

and damages sustained by the Plaintiffs. Plaintiffs will amend this complaint to allege the true names and capacities of said DOE defendants when that same is ascertained.

7. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, each of the defendants and each of the DOE defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE defendants, and each of them, and at all said times, each defendant and each DOE defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

8. Plaintiffs are informed and believe, and thereon allege, that all times mentioned herein, defendants and DOES 1 through 100, and each of them, inclusive, were also known as, formerly known as and/or were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were members in an entity or entities engaged in the funding, researching, studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging and advertising a certain substance, the generic name of which is Actos. Defendants and DOES 1 through 100, and each of them, inclusive, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that defendants and DOES 1 through 100, and each of them, inclusive, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or portion thereof), and in that there has been a virtual destruction of Plaintiff's remedy against each such alternate entity, and that each such defendant has the ability to assume the risk spreading role of each such alternate entity.

9. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, Defendants and DOES 1 through 100, and each of them, inclusive, were and are corporations organized and existing under the laws of the State of California or the laws of some

state or foreign jurisdiction; that each of the said Defendants and DOE defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in this State, Los Angeles County and San Diego County.

10. Upon information and belief, at relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, and including Los Angeles County and San Diego County either directly or indirectly through third parties or related entities, its products, including Actos and pioglitazone hydrochloride.

11. At relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, conducted regular and sustained business and engaged in substantial commerce and business activity in the State of California, which included but was not limited to selling, marketing and distributing its products including Actos and pioglitazone hydrochloride in the State of California, and including Los Angeles County and San Diego County.

12. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, inclusive, expected or should have expected that their acts would have consequences within the United States of America including the State of California, including Los Angeles County and San Diego County, and Defendants derived and derive substantial revenue therefrom.

13. At all relevant times alleged herein Plaintiffs WILLIAM PIERCE and SHARON PIERCE were, and are, legally married and residents of Harrodsburg, Kentucky.

14. Defendant TAKEDA PHARMACEUTICALS AMERICA is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

15. Upon information and belief, Defendant TAKEDA PHARMACEUTICALS NORTH AMERICA, INC. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times alleged herein, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC. was involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

16. Defendant TAKEDA PHARMACEUTICALS INTERNATIONAL, INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. At all relevant times alleged herein TAKEDA PHARMACEUTICALS INTERNATIONAL, INC. was involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

17. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. At all relevant times alleged herein, TAKEDA PHARMACEUTICAL COMPANY LIMITED was engaged in the research, development, sales, and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

18. Defendant TAKEDA PHARMACEUTICALS, LLC. is a Delaware limited liability company with a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times alleged herein, TAKEDA PHARMACEUTICALS, LLC. was involved in the business of research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

19. Defendant TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. At all relevant times alleged herein TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC. was involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

20. Defendant TAKEDA CALIFORNIA, INC., fka TAKEDA SAN DIEGO, INC., is a Delaware corporation, having its principal place of business at 10410 Science Center Drive, San Diego, CA 92121. At all relevant times alleged herein TAKEDA CALIFORNIA, INC. was involved in the testing, monitoring, research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

21. ELI LILLY AND COMPANY is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana, 46285.

22. Upon information and belief, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a company domiciled in Japan and is the parent/holding company of Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS, LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., and TAKEDA CALIFORNIA, INC. fka TAKEDA SAN DIEGO, INC.

23. Upon information and belief, at all relevant times, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED exercised and exercises dominion and control over Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS, LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., and TAKEDA CALIFORNIA, INC.

24. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED expected or should have expected that its acts would have consequences within the United States of America, the State of California, Los Angeles County and San Diego County and derive substantial revenue from interstate commerce.

25. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED have transacted and conducted business in the State of California and/or contracted to supply goods and services within the State of California, including Los Angeles County and San Diego County and these causes of action have arisen from same.

26. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED committed a tortious act without the State of California causing injury within the State of California out of which act(s) these causes of action arise.

27. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL

COMPANY LIMITED committed tortious act(s) within the State of California out of which act(s) these causes of action arise.

28. Takeda California is a Delaware corporation with its principal place of business located at 10410 Science Center Drive, San Diego, CA 92121. At all relevant times alleged herein, Takeda California and its predecessor companies were involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

29. Takeda California is a wholly owned subsidiary of Takeda Limited.

30. Takeda California has transacted and conducted business throughout the United States and the State of California.

31. Takeda California has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Kentucky.

32. Takeda California expected or should have expected its acts to have consequences throughout the United States and the State of California, and derived substantial revenue from interstate commerce.

33. Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

34. Lilly has transacted and conducted business throughout the United States and the State of California.

35. Lilly has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of California.

36. Lilly expected or should have expected its acts to have consequences throughout the United States and the State of California, and derived substantial revenue from interstate commerce.

37. From February 2005 through January 2011, Plaintiff took Actos manufactured and distributed by Defendants for treatment of Type 2 diabetes.

38. As a result of the defective nature of Actos, persons who were prescribed and who subsequently ingested this product, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

39. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer associated with Actos.

40. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiffs' injuries and damages. Plaintiffs accordingly seek damages associated with these injuries.

FACTUAL ALLEGATIONS

41. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos, for the treatment of Type 2 diabetes mellitus.

42. According to the American Diabetes Association, Type 2 diabetes is the most common form of diabetes. Type 2 diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type 1 diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

43. Actos was jointly launched by Takeda North America and Lilly in 1999.

44. Actos was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat Type 2 diabetes.

45. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZDs").

46. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos.

47. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat Type 2 diabetes and should not be used to treat Type 1 diabetes.

48. Actos is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

49. Prior to Actos being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.

50. The Actos NDA Pharmacology Review includes a special discussion on neoplastic lesions, which states: "Various tissues of control and treated groups had usual types of mouse tumors. Peto analysis of neoplastic lesions present in this study revealed 2 tumor types that were significant ($P < 0.05$)." "In mouse lymphoma assays, metabolite M-I produced a positive response in the presence of metabolic activation and an equivocal response..."

51. According to the Actos NDA Medical Review section, one patient reported with bladder cancer and fourteen patients reported to have category C3 cytology in their urine from US trials. (Cytology is a study of cells to diagnose cancer. C3 is probably benign with suspicion of malignancy, and C4 is malignancy. Some authors believe that C3 and C4 should be categorized in the same group).

52. Urine cytology tests were not amongst the exclusion criteria for the early studies of Actos (e.g., Study PNFP 001). However, in order to reduce the number of bladder cancers reported from the Actos clinical trials and thereby enable the company to create a better safety profile for regulatory approval, Takeda amended the patient enrollment criteria in the middle of the phase III trials and added the urine cytology test as an exclusion criteria.

53. Having used cytology testing during the Phase III clinical trials to exclude persons at risk for developing bladder cancer following exposure to Actos, Takeda was obligated to include cytology testing as a pre-requisite for prescribing Actos to prospective patients.

54. All persons placed on Actos since 1999 who were not given cytology screening have been unnecessarily exposed to the risk of developing bladder cancer which could have been avoided, but for Takeda's efforts to deceitfully suppress the appearance of bladder cancers during the Actos NDA clinical trials by excluding persons with positive cytology testing results.

55. Once Takeda received Actos marketing approval in July 1999, recommending urine cytology tests was never included in the package insert to warn patients of the risk of developing bladder cancer while on Actos in the absence of such testing. At the very least, Takeda should have

discussed this with the FDA when submitting its first Actos labeling change in order to warn the public. Instead, Takeda chose to keep quiet and later deny any causal link between Actos and cancer.

56. Takeda was reminded of Actos' bladder cancer risk, but chose not to warn of the risk, when an article published in the January 2003 edition of the Southern Medical Journal, entitled "Thiazolidinediones: A Review of Their Benefits and Risks" by Fernando Ovalle, MD, J., suggested that, as a class risk, neoplastic potential based on animal studies showed "TZDs may induce the formation of lipomas, benign and/or malignant urinary bladder (transitional cell) tumors, vascular tumors...and the growth of uterine leiomyomas."

57. Takeda was directed by the FDA to conduct a Post Marketing Commitment (PMC) study regarding Actos and bladder cancer, however, Takeda delayed initiating such a trial until 2003 at Yale University. It was constructed as a 10-year trial, so the results of the study would not be available until after Takeda's exclusive Actos patent had expired, after exposing Actos patients to 13 years of non-cytology screened exposure to Actos.

58. Thus, in the end, Takeda would receive the benefit of tens of billions of dollars in Actos sales while awaiting the bladder cancer results.

59. In 2005, the results of the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial,* The Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

60. The PROactive study was looking at cardiovascular events and outcomes.

61. During the course of monitoring the study, the researchers and Defendants became aware that there was a statistically significant demonstrated higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

62. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increases of bladder cancer.

63. This information was not included in the published Dormandy paper.

64. Takeda never issued a Dear Doctor Letter to the medical community regarding the risk of bladder cancer and only added a clause to the label that 16 bladder cancers were reported from the PROactive study, while denying the causality associated with administration of Actos.

65. Since the original label in 1999, the Actos label has included the same wording: "Drug-induced tumors were not observed in any organ except for the urinary bladder. Benign and/or malignant transitional cell neoplasm were observed in male rats at 4 mg/kg/day and above (approximately equal to the maximum recommended human dose based on mg/m^2)." To this day, however, Takeda's Actos label states: "There are too few events of bladder cancer to establish causality."

66. After the FDA approved Actos for marketing in the US, Takeda received an average of more than 180 cancer reports each year (1,813 over 10 years) from spontaneous sources, but Takeda never included these cancer reports in the label, and never issued a Dear Doctor letter in the last 10 years to warn the medical community of the risk of developing cancer while taking Actos.

67. Moreover, during a post marketing commitment study conducted at Yale University, at least 10 bladder cancer cases were reported. The Yale study had enrolled more than 40 patients who were diagnosed with bladder cancer while taking Actos. The Yale clinical investigator reported these events as related to Actos. When a medical reviewer in Takeda's pharmacovigilence department attempted to report one of these cases as "related," she was told to change her assessment to "unrelated."

68. This same medical reviewer conducted an analysis of Takeda's ARISg database and determined there was an estimated 100 or more bladder cancers that were reported to the company, but only 72 were reported to the FDA.

69. On September 17, 2010, the FDA issued a Safety Communication stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use, reaching statistical significance after 24 months.

70. In addition, a three-year liver safety study was performed, and according to the FDA's September Safety Communication, that study demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

71. Despite the FDA finding that Actos is linked to a statistically significant increase in the risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study had not shown a risk to patients of bladder cancer or other cancers from Actos.

72. In early 2011, the American Diabetes Association published Piccinni, *et al. Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting,* Diabetes Care, 34:1369-1371 (June 2011), published ahead of print on April 22, 2011. This study looked at adverse event reports made to the FDA between 2004 and 2009.

73. Piccinni, *et al.* analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone.

74. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

75. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk."

76. In the April 22, 2011 edition of Diabetes Care, an analysis of the FDA's AERS was published finding that one fifth of the 138 bladder cancer reports for all drugs submitted between 2004 and 2009 were regarding patients taking Actos. According to the study author, Dr. Elisabeta Poluzzi, this indicates a disproportionate risk of bladder cancer for patients taking Actos, warranting additional investigation.

77. The Poluzzi study used a "disproportionate risk" analysis, which is a method used to detect signals of causality assessments related to spontaneous reports. ALL of the cancers reported

from Actos in the AERSg were disproportionally higher than the background rate to a very substantial degree.

78. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review.

79. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than a year. The French cohort included 1.5 million patients with diabetes who were followed for four years (2006-2009).

80. On June 10, 2011, Reuters published a story announcing that Germany had joined France in suspending the use of Actos after Germany's Federal Institute for Drugs and Medical Devices ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

81. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA also ordered Takeda to include information about this risk to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

82. Again, the FDA reported that the risk of bladder cancer increased with increasing doses and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposure to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

83. On July 12, 2011, Takeda Limited issued a recall of Actos in France.

84. Following the recall in France, Takeda Limited refused to issue a recall of Actos in the United States thereby continuing to subject American citizens to the significant risk of

developing bladder cancer while ensuring the users in France and Germany were no longer subject to this risk.

85. As the manufacturers of Actos, Defendants knew or should have known that Actos use was associated with bladder cancer.

86. With the knowledge of the true relationship between use of Actos and developing bladder cancer, rather than take steps to pull the drug off the market or to issue stronger warnings, Defendants promoted Actos as a safe and effective treatment for Type 2 diabetes.

87. Despite its knowledge that Actos increases the risk of patients developing bladder cancer, Defendants refused to warn patients, physicians and the medical community about the risk of developing bladder cancer, and in fact continuously denied causality.

88. Actos is one of Defendants' top selling drugs. Upon information and belief, in the last year, global sales of Actos reached $4.8 billion and accounted for approximately 27% of Takeda's revenue.

89. In 2008, with the knowledge that Actos was associated with an increased risk of patients developing bladder cancer, Takeda Limited achieved its marketing goal by making Actos the tenth best-selling medication in the United States all while placing American citizens at risk of developing bladder cancer.

90. Consumers, including Plaintiff, who have used Actos for treatment of Type 2 diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits, associated with Actos therapy.

91. In 2005, Plaintiff was prescribed and began taking Actos upon direction of his physician for maintenance of Type 2 diabetes.

92. Plaintiff subsequently developed bladder cancer in April 2009.

93. Plaintiff ceased using Actos in January 2011.

94. Defendants concealed their knowledge that Actos can cause bladder cancer from Plaintiff, his treating medical providers, other consumers, and the medical community in general.

95. Defendants did not adequately inform Plaintiff, other consumers and the prescribing medical community about the risks of bladder cancer with use of Actos.

96. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with Actos therapy.

97. As a result of Defendants' actions, Plaintiff and his physicians were unaware, and could not have reasonably known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

98. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its use.

99. As a direct result of being prescribed Actos for many years, Plaintiff has been permanently and severely injured, having suffered serious consequences from Actos use.

100. Plaintiff, as a direct and proximate result of Actos use, suffered severe mental and physical pain and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses and living related expenses as a result of his new lifestyle.

101. Plaintiff requires and will in the future require ongoing medical care and treatment.

102. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Actos.

103. With respect to the prescription drug Actos, the Defendants, upon information and belief, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs, including but not limited to one or more of the following violations:

a) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on the labels.

c) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g) The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5 because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used; (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions; (c) frequency of administration or application, (d) duration or administration or application; (e) time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors); (f) route or method of administration or application (g) preparation for use, i.e., shaking dilution, adjustment of temperature, or, other manipulation or process. 21 CFR § 201.5.

h) The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i) The prescription drug Actos is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j) The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

k) The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved, for certain narrow situations, if at all, and the Defendants failed to state such information.

l) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

m) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

n) The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

o) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

p) The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be

used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety, have the identity and strength, and meets the quality and purity characteristic that they purport or are represented to possess.

q) The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

r) The prescription drug Actos violates 21 CFR §211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

s) The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

t) The prescription drug Actos violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

u) The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.

v) The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

w) The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

x) The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

y) The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

z) The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

aa) The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

bb) The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

cc) The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

dd) The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

104. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under Kentucky and California law.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants and DOES 1 through 100)

105. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

106. Defendants and DOES 1 through 100, and each of them, inclusive, had a duty to Plaintiffs to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Actos and pioglitazone hydrochloride into the stream of commerce, including a duty to assure that Actos and pioglitazone hydrochloride would not cause users to suffer unreasonable, dangerous side effects such as cancer.

107. Defendants and DOES 1 through 100, and each of them, inclusive, failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, quality assurance, quality control, and/or distribution of Actos into interstate commerce in that Defendants knew or should have known that using Actos caused a risk of unreasonable, dangerous side effects, including bladder cancer.

108. Despite the fact that Defendants and DOES 1 through 100, and each of them, inclusive, knew or should have known that Actos was associated with and caused bladder cancer, Defendants continued to market, manufacture, distribute and/or sell Actos to consumers, including the Plaintiff.

109. Defendants and DOES 1 through 100, and each of them, inclusive, knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of said Defendants' failure to exercise ordinary care, as set forth above.

110. Defendants' and DOES 1 through 100, and each of their, inclusive, negligence and/or recklessness was a substantial factor and legal and proximate cause of Plaintiff's injuries, harm and economic loss which he suffered and/or will continue to suffer.

111. The conduct of the Defendants and DOES 1 through 100, and each of them, inclusive, as described in this cause of action was a substantial factor and legal and proximate cause of the injuries and damages sustained by Plaintiff, and that said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and that such intentional acts and omissions were substantial factors in causing his disease and injuries.

112. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE has suffered, and continues to suffer, permanent injuries to his person, body and health, including but not limited to, serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, all to his general damage in a sum in excess of the jurisdictional limits of this Court.

113. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE was and will be compelled to and did employ medical and/or hospital care, attention, and services, including but not limited to, lifelong medical treatment, monitoring and/or medications, in an amount which has not as yet been fully ascertained and which will be asserted according to proof at trial.

114. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs have and/or will suffer loss of income and earnings, past, present and future and earning capacity in an amount which has not as yet been fully ascertained and which will be asserted according to proof at trial.

115. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs did necessarily incur and in the

future will incur incidental expenses and damages in an amount which has not as yet been fully ascertained and which will be asserted according to proof at trial.

116. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof at trial.

117. Plaintiffs are informed and believe and based thereon allege that in doing the acts alleged in this complaint, the Defendants, and each of them, acted with oppression, fraud, and malice, and Plaintiffs are therefore entitled to punitive damages to deter the Defendants, and each of them, and others from engaging in similar conduct in the future. The wrongful conduct described herein was undertaken with the advance knowledge, authorization, or ratification of an officer, director, or managing agent of Defendants, and each of them.

118. Plaintiffs maintain and reserve their rights to plead additional facts, theories of liability, causes of action in their complaint, and/or to present evidence pertaining to the acts and omissions of Defendants as may be subsequently identified through discovery and investigation in this matter. Plaintiffs reserve the right to present such evidence at the time of trial based upon such subsequently discovered acts, omissions or damages that are heretofore unknown or unidentified prior to the date of service of this complaint and maintain and reserve their rights to thereafter move the court to conform pleadings to proof in this matter.

SECOND CAUSE OF ACTION

STRICT LIABILITY - FAILURE TO WARN

(Against All Defendants and DOES 1 through 100)

119. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

120. Defendants and DOES 1 through 100, and each of them, inclusive, researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed,

and/or introduced Actos into the stream of commerce, and in the course of same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of the Product.

121. Defendants and DOES 1 through 100, and each of them, inclusive, had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Actos and pioglitazone hydrochloride and/or are associated with the use of Actos and pioglitazone hydrochloride.

122. The Actos and pioglitazone hydrochloride manufactured and/or supplied by the Defendants and DOES 1 through 100, and each of them, inclusive, was defective due to inadequate post-marketing warnings and/or instructions because, after the said Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote Actos.

123. Due to the inadequate warning regarding bladder cancer, Actos was in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants and DOES 1 through 100, and each of them, inclusive.

124. Defendants and DOES 1 through 100, and each of them, inclusive, failed to adequately warn Plaintiff and Plaintiff's prescribing physicians of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

125. Defendants' and DOES 1 through 100, and each of their, inclusive, failure to adequately warn Plaintiff and Plaintiff's prescribing physicians of a bladder cancer risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

126. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' and DOES 1 through 100, and each of them, inclusive, Actos and pioglitazone hydrochloride, Plaintiff would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

127. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of the Defendants' and DOES 1 through 100, and each of their, inclusive, their drug Actos and pioglitazone hydrochloride, Plaintiff's prescribing physicians would have discussed the risks of bladder cancer and Actos with the Plaintiff and/or would not have prescribed it.

128. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff was caused to suffer from the aforementioned injuries and damages.

129. The failure to warn by Defendants and DOES 1 through 100, and each of them, inclusive, was a substantial factor and legal and proximate cause of Plaintiff WILLIAM PIERCE's injuries and damages thereby sustained by Plaintiff, and that said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and that such intentional acts and omissions were substantial factors in causing his disease and injuries.

130. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE suffered severe and permanent injuries to his person, and Plaintiff suffered damages as alleged above.

131. In particular, Plaintiff would show that, as alleged here in this cause of action and throughout this complaint, that such intentional, grossly wanton acts and omissions by defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors in causing his disease and injuries. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

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THIRD CAUSE OF ACTION

STRICT LIABILITY - DEFECTIVE DESIGN

(Against All Defendants and DOES 1 through 100)

132. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

133. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants and DOES 1 through 100, and each of them, inclusive.

134. At all times relevant, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

135. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants and DOES 1 through 100, and each of them, inclusive, was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actos.

136. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants and DOES 1 through 100, and each of them, inclusive, was defective in design and formulation, because when it left the hands of said Defendants' manufacturers and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

137. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants and DOES 1 through 100, and each of them, inclusive, knew and had reason to know that the product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by said Defendants.

138. Defendants and DOES 1 through 100, and each of them, inclusive, had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

139. At the time of Plaintiff's use of Actos, it was being used for its intended purpose, and in a manner normally intended, namely for the treatment of Type 2 Diabetes Mellitus.

140. Defendants and DOES 1 through 100, and each of them, researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff in particular, and said Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

141. At the time Defendants' and DOES 1 through 100, and each of their, inclusive, product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Actos. This was demonstrated by the existence of other Type 2 Diabetes Mellitus medications which had a more established safety profile and a considerably lower risk profile.

142. Plaintiff could not, by the reasonable exercise of care, have discovered Actos' defects and perceived its danger.

143. The defects in the product of Defendants and DOES 1 through 100, and each of them, inclusive, were substantial and contributing factors in causing Plaintiff's injuries.

144. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff was caused to suffer from the aforementioned injuries and damages.

145. Due to the unreasonably dangerous condition of Actos, Defendants and DOES 1 through 100, and each of them, inclusive, are strictly liable to Plaintiff.

146. The product defect in the product of the Defendants and DOES 1 through 100, and each of them, inclusive, was a substantial factor and legal and proximate cause of Plaintiff WILLIAM PIERCE's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

147. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE suffered severe and permanent injuries to his person, and Plaintiff suffered damages as alleged herein above.

148. In particular, Plaintiff would show that, as alleged here in this cause of action and throughout this complaint, such intentional, grossly wanton acts and omissions by defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors in causing his disease and injuries. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants and DOES 1 through 100)

149. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

150. Defendants and DOES 1 through 100, and each of them, inclusive, expressly warranted that Actos was safe for its intended use and as otherwise described in this complaint. Actos did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects like bladder cancer, that it would improve health, maintain health, and potentially prolong life.

151. The express warranties represented by the Defendants and DOES 1 through 100, and each of them, inclusive, were a part of the basis for Plaintiff's use of Actos and Plaintiff relied on these warranties in deciding to use Actos.

152. At the time of the making of the express warranties, the Defendants and DOES 1 through 100, and each of them, inclusive, had knowledge of the purpose for which the Actos and pioglitazone hydrochloride was to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

153. Defendants and DOES 1 through 100, and each of them, inclusive, breached the above-described express warranty in that Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among other things bladder cancer, degrading Plaintiff's health, and shrinking his life expectancy.

154. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, as described in this cause of action were substantial factors and legal and proximate causes of the injuries and damages sustained by Plaintiff.

155. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors and legal and proximate causes of Plaintiff WILLIAM PIERCE's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

156. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE suffered severe and permanent injuries to his person, and Plaintiff suffered damages as alleged above.

157. In particular, Plaintiff would show that, as alleged here in this cause of action and throughout this complaint, that such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors in causing his disease and injuries. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff

WILLIAM PIERCE, such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

(Against All Defendants and DOES 1 through 100)

158. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

159. At all times herein mentioned, the Defendants and DOES 1 through 100, and each of them, inclusive, manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

160. The Defendants and DOES 1 through 100, and each of them, inclusive, impliedly represented and warranted to the users of Actos that Actos was safe and fit for the particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

161. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

162. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

163. Plaintiff reasonably relied upon the skill and judgment of Defendants and DOES 1 through 100, and each of them, inclusive, as to whether Actos was safe and fit for its intended use.

164. Actos and pioglitazone hydrochloride were injected into the stream of commerce by the Defendants and DOES 1 through 100, and each of them, inclusive, in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

165. Defendants and DOES 1 through 100, and each of them, inclusive, breached the aforesaid implied warranty, as their drug Actos was not fit for its intended purposes and uses.

166. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, as described in this cause of action was a substantial factor and legal and proximate cause of the injuries and damages sustained by Plaintiff.

167. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors and legal and proximate causes of Plaintiff WILLIAM PIERCE's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

168. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors and legal and proximate causes of Plaintiff 's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

169. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE suffered severe and permanent injuries to his person, and Plaintiff suffered damages as alleged herein above.

170. In particular, Plaintiff would show that, as alleged here in this cause of action and throughout this complaint, that such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors in causing his disease and injuries. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

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SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants and DOES 1 through 100)

171. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations all of the preceding paragraphs.

172. Defendants and DOES 1 through 100, and each of them, inclusive, manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

173. Defendants and DOES 1 through 100, and each of them, inclusive, marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by Plaintiff and impliedly warranted to Plaintiff that Actos was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

174. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

175. Plaintiff reasonably relied on the skill, expertise and judgment of the Defendants and DOES 1 through 100, and each of them, inclusive, and their representations as to the fact that Actos was of merchantable quality.

176. The Actos and pioglitazone hydrochloride manufactured and supplied by the Defendants and DOES 1 through 100, and each of them, inclusive, was not of merchantable quality, as warranted by the Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

177. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, as described in this cause of action was a substantial factor and legal and proximate cause of the injuries and damages sustained by Plaintiff.

178. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors and legal and proximate causes of Plaintiff WILLIAM

PIERCE's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

179. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors and legal and proximate causes of Plaintiff WILLIAM PIERCE's injuries and damages thereby sustained by Plaintiff, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE, and such intentional acts and omissions were substantial factors in causing his disease and injuries.

180. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiff WILLIAM PIERCE suffered severe and permanent injuries to his person, and Plaintiff suffered damages as alleged above.

181. In particular, Plaintiff would show that, as alleged here in this cause of action and throughout this complaint, that such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, inclusive, were substantial factors in causing his disease and injuries. As the above referenced conduct complained of in this complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff WILLIAM PIERCE such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

SEVENTH CAUSE OF ACTION

VIOLATION OF CAL. BUSINESS & PROFESSIONS CODE §17200, et seq.

(Against All Defendants and DOES 1 through 100)

182. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

183. Plaintiffs bring this cause of action pursuant to Business & Professions Code §17204, in an individual capacity, and not on behalf of the general public.

184. California Business & Professions Code §17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

185. The acts and practices described in Paragraphs 1 through 118 above, were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of Business and Professions Code §17200. The acts of untrue and misleading advertising set forth in preceding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code §17200. This conduct includes, but is not limited to:

(a) Representing to Plaintiff, Plaintiff's physicians and the general public that Actos and pioglitazone hydrochloride were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that said products had a serious propensity to cause injuries to users;

(b) Engaging in advertising programs designed to create the image, impression and belief by consumers, and physicians that the use of Actos and pioglitazone hydrochloride was safe for human use, had fewer side effects and adverse reactions than other Type 2 Diabetes medications, constituted a convenient safe form even though the Defendants and DOES 1 through 100, and each of them, inclusive, knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;

(c) Purposely downplaying and understating the health hazards and risks associated with Actos and pioglitazone hydrochloride.

186. As a result of their conduct described above Defendants and DOES 1 through 100, and each of them, inclusive, have been and will be unjustly enriched. Specifically, said Defendants have been unjustly enriched by receipt of billions of dollars in ill-gotten gains from the sale and prescription of said drugs in California, sold in large part as a result of the acts and omissions described herein.

187. Because of the misrepresentations made by Defendants and DOES 1 through 100, and each of them, inclusive, as detailed above, and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, the acts of said Defendants described herein constitute unfair or fraudulent business practices.

188. Plaintiff, pursuant to California Business & Professions Code §17203, seeks an order of this court compelling the Defendants and DOES 1 through 100, and each of them, inclusive, to provide restitution, and to disgorge the monies collected and profits realized by said Defendants as a result of their unfair business practices, and injunctive relief calling for said Defendants, and each of them, to cease such unfair business practices in the future.

EIGHTH CAUSE OF ACTION

VIOLATION OF CAL. BUSINESS & PROFESSIONS CODE §17500, et seq.

(Against All Defendants and DOES 1 through 100)

189. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

190. Plaintiffs bring this cause of action pursuant to Business & Professions Code §17535, in an individual capacity and not on behalf of the general public.

191. California Business & Professions Code §17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

192. At all times herein mentioned Defendants and DOES 1 through 100, and each of them, inclusive, have committed acts of disseminating untrue and misleading statements as defined by Business & Professions Code §17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Actos and pioglitazone hydrochloride:

(a) Representing to Plaintiff, Plaintiff's physicians and the general public that Actos and pioglitazone hydrochloride were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff,

Plaintiff's physicians and the general public that said products had a serious propensity to cause injuries to users;

(b) Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Actos and pioglitazone hydrochloride was safe for human use, had fewer side effects and adverse reactions than other Type 2 Diabetes medications, constituted a convenient safe form even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;

(c) Purposely downplaying and understating the health hazards and risks associated with Actos and pioglitazone hydrochloride.

193. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code §17500.

194. The acts of untrue and misleading statements by Defendants and DOES 1 through 100, and each of them, inclusive, described herein above present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.

195. As a result of their false and misleading statements described above, Defendants and DOES 1 through 100, and each of them, inclusive, have been and will be unjustly enriched. Specifically, said Defendants have been unjustly enriched by billions of dollars in ill-gotten gains from the sale and prescription of Actos and pioglitazone hydrochloride, sold in large part as a result of the false or misleading statements described herein.

196. Pursuant to California Business & Professions Code §17535, Plaintiff seek an order of this court compelling the Defendants and DOES 1 through 100, and each of them, inclusive, to provide restitution, and to disgorge the monies collected and profits realized by said Defendant, and each of them, as a result of their unfair business practices, and injunctive relief calling for said Defendants, and each of them, to cease such unfair business practices in the future. Plaintiff seeks the imposition of a constructive trust over, and restitution and disgorgement of, monies collected

and profits realized by said Defendants, and each of them, to cease such false and misleading advertising in the future.

NINTH CAUSE OF ACTION

DECEIT BY CONCEALMENT

(Against All Defendants and DOES 1 through 100)

197. Plaintiffs re-allege and incorporate herein by reference the foregoing paragraphs of this Complaint and further states as follows:

198. From the time that Actos was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants and DOES 1 through 100, and each of them, inclusive, willfully deceived Plaintiff by concealing from the Plaintiff, Plaintiff's health care providers and the general public, the true facts concerning Actos, which the Defendants had a duty to disclose.

199. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of Actos and pioglitazone hydrochloride (hereinafter "PRODUCT") and willfully deceived Plaintiff, Plaintiff's physicians and the general public that the health risks and consequences of the use of the PRODUCT were hazardous to health, and that the PRODUCT has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Plaintiff as described herein.

200. Defendants intentionally concealed and suppressed the true facts concerning the PRODUCT with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not have prescribed the PRODUCT and Plaintiff would not have used the PRODUCT if Plaintiff had known the true facts concerning the dangers of the PRODUCT.

201. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiffs suffered injuries and damages as described herein.

TENTH CAUSE OF ACTION

NEGLIGENT AND INTENTIONAL MISREPRESENTATION

(Against All Defendants and DOES 1 through 100)

202. Plaintiffs re-allege and incorporate herein by reference the foregoing paragraphs of

this Complaint and further states as follows:

203. Defendants, and each of them, from the time that the PRODUCT was first tested, studied, researched, manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to Plaintiff, Plaintiff's health care providers, and the general public including, but not limited to, the misrepresentation that the PRODUCT was safe, fit, and effective for human consumption.

204. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the PRODUCT and willfully deceive Plaintiff, Plaintiff's health care providers, and the general public as to the health risks and consequences of the use of the PRODUCT.

205. Defendants made the foregoing misrepresentations knowing them to be false or without any reasonable ground for believing them to be true. These misrepresentations were made directly by Defendants, by sales representatives and other authorized agents of said Defendants, and in publications and other written materials directed to physicians, patients, and the general public, with the intention of inducing reliance and the prescription, purchase, and use of the PRODUCT.

206. The foregoing representations by Defendants, and each of them, were in fact false, in that the PRODUCT is not, and at all relevant times alleged herein, was not safe, fit, and effective for human consumption, and that the use of the PRODUCT is hazardous to health, and that the PRODUCT has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Plaintiffs as described herein. The foregoing misrepresentations by Defendants, and each of them, were made with the intention of inducing reliance and inducing the prescription, purchase, and use of the PRODUCT.

207. In reliance on the misrepresentations by Defendants, and each of them, Plaintiffs were induced to purchase and use the PRODUCT. If Plaintiffs had known of the true facts concealed by Defendants, Plaintiffs would not have used the PRODUCT. The reliance by Plaintiffs upon Defendants' misrepresentations was justified because such misrepresentations were made by Defendants through individuals and entities that were in a position to know the true facts.

208. As a result of the foregoing negligent and intentional misrepresentations by

Defendants, and each of them, Plaintiffs suffered injuries and damages as described above. Defendants' conduct was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiff such that, Plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

ELEVENTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA *CIVIL CODE* §§ 1750 ET. SEQ

(Against All Defendants and DOES 1 through 100)

209. Plaintiffs re-allege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

210. Plaintiffs are informed and believe and thereon allege that Defendants, and each of them, by the acts and misconduct alleged herein, violated the Consumers Legal Remedies Act, California Civil Code §§ 1750 et. seq. ("CLRA").

211. Plaintiffs hereby seek injunctive relief as appropriate against Defendants, and each of them, for their violations of California Civil Code §§ 1750 et. seq. The CLRA applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, or which have resulted, in the sale of goods to consumers.

212. Plaintiffs are "consumers" within the meaning of California Civil Code § 1761(d).

213. Defendants have violated, and continue to violate, the CLRA in representing that goods have characteristics and benefits which they do not have, in violation of California Civil Code § 1770(a)(5).

214. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California Civil Code § 1770, by engaging in the following acts and practices with intent to induce members of the public to purchase and use the PRODUCT: by engaging in the following acts and practices with intent to induce members of the public to purchase and use Actos and pioglitazone hydrochloride:

(a) Representing to Plaintiff, Plaintiff's physicians and the general public that Actos and pioglitazone hydrochloride were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that said products had a serious propensity to cause injuries to users;

(b) Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Actos and pioglitazone hydrochloride was safe for human use, had fewer side effects and adverse reactions than other Type 2 Diabetes medications, constituted a convenient safe form even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;

(c) Purposely downplaying and understating the health hazards and risks associated with Actos and pioglitazone hydrochloride.

215. The foregoing practices constitute false and misleading advertising and representations within the meaning of California Civil Code § 1770. The acts of untrue and misleading statements by Defendants described herein present a continuing threat to members of the public and individual consumers in that the acts alleged herein are continuous and ongoing, and the public and individual consumers will continue to suffer harm as alleged herein.

216. Unless Defendants are enjoined from continuing to engage in these violations of the CLRA, Plaintiffs will continue to be harmed by the wrongful actions and conduct of Defendants. Pursuant to California Civil Code § 1780, Plaintiffs seek an order of this court for injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices in the future.

TWELFTH CAUSE OF ACTION

VIOLATION OF KENTUCKY CONSUMER PROTECTION ACT, KY. REV. STAT. SECTION 376.170 et al.

(Against All Defendants and DOES 1 through 100)

217. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

218. Plaintiffs bring this cause of action pursuant to Kentucky Revised Statute Section 376.170 et. al.

219. Kentucky Revised Statute Section 376.170 provides that "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

220. At all times herein mentioned Defendants and DOES 1 through 100, and each of them, inclusive, have violated Kentucky Revised Statute Section 376.170 by engaging in the following unfair, false, misleading and deceptive acts and practices with intent to induce members of the public to purchase and use Actos and pioglitazone hydrochloride:

(a) Representing to Plaintiff, Plaintiff's physicians and the general public that Actos and pioglitazone hydrochloride were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that said products had a serious propensity to cause injuries to users;

(b) Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Actos and pioglitazone hydrochloride was safe for human use, had fewer side effects and adverse reactions than other Type 2 Diabetes medications, constituted a convenient safe form even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;

(c) Purposely downplaying and understating the health hazards and risks associated with Actos and pioglitazone hydrochloride.

221. The foregoing practices constitute unfair, false, misleading and deceptive acts within the meaning of Kentucky Revised Statute Section 376.170.

222. The acts of untrue and misleading statements by Defendants and DOES 1 through 100, and each of them, inclusive, described herein above present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.

223. As a result of their false and misleading statements described above, Defendants and DOES 1 through 100, and each of them, inclusive, have been and will be unjustly enriched. Specifically, said Defendants have been unjustly enriched by billions of dollars in ill-gotten gains from the sale and prescription of Actos and pioglitazone hydrochloride, sold in large part as a result of the false or misleading statements described herein.

224. Plaintiff seek an order of this court compelling the Defendants and DOES 1 through 100, and each of them, inclusive, to provide restitution, and to disgorge the monies collected and profits realized by said Defendant, and each of them, as a result of their unfair business practices, and injunctive relief calling for said Defendants, and each of them, to cease such unfair business practices in the future. Plaintiff seeks the imposition of a constructive trust over, and restitution and disgorgement of, monies collected and profits realized by said Defendants, and each of them, to cease such false and misleading advertising in the future. Plaintiff further seeks compensatory damages, punitive damages and reasonable attorneys' fees and costs as a result of Defendants violations of the Kentucky Consumer Protection Act.

THIRTEENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(Against All Defendants and DOES 1 through 100)

225. Plaintiffs re-allege and incorporate here by reference, as though fully set forth at length herein, all of the allegations of all of the preceding paragraphs.

226. Plaintiff WILLIAM PIERCE became legally married to Plaintiff SHARON PIERCE on November 4, 1996 and, at all relevant times alleged herein the Plaintiffs were, and are, legally married to one another.

227. As a direct and proximate result of the injuries and damages alleged herein, Plaintiff SHARON PIERCE was deprived of the comfort and enjoyment of the services and society of her legal spouse Plaintiff WILLIAM PIERCE, and has suffered and will continue to suffer general and special damages including, but not limited to, economic loss, and has otherwise been emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiffs seek general, compensatory, special and punitive damages from the

Defendant as alleged herein.

228. At all relevant times alleged herein Plaintiff SHARON PIERCE was and is the lawful spouse of Plaintiff WILLIAM PIERCE and, as such, was and is entitled to the comfort, enjoyment, society and services.

229. Plaintiff WILLIAM PIERCE sustained injuries caused by Actos. Prior to the aforesaid injuries, Plaintiff WILLIAM PIERCE was able to and did perform duties as a spouse to Plaintiff SHARON PIERCE.

230. Subsequent to the injuries, and as a proximate result thereof, Plaintiff WILLIAM PIERCE was unable to perform the necessary duties as a spouse and the work and service usually performed in the care, maintenance and management of the family home, and therefore has sustained special damages in an amount which has not as yet been fully ascertained and which will be asserted according to proof at trial.

231. Subsequent to the injuries, and as a proximate result thereof, Plaintiff SHARON PIERCE suffered loss of consortium, including, but not by way of limitation, loss of services, marital relations, society, comfort, companionship, love and affection of her said spouse, and has suffered severe mental and emotional distress and general nervousness as a result thereof.

232. As the above referenced conduct complained of in this complaint of Defendants and DOES 1 through 100, and each of them, inclusive, was and is vile, base, willful, malicious, fraudulent, oppressive, outrageous, and that said defendants, and each of them, demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of plaintiff WILLIAM PIERCE, such that plaintiff, for the sake of example, and by way of punishing said defendants, seeks punitive damages according to proof.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray judgment against Defendants, and DOES 1 through 100, and each of them, inclusive, as follows:

1. For general damages according to proof;

2. For special damages according to proof;

3. For medical and related expenses according to proof;

4. For loss of income, earning capacity, earning potential according to proof;

5. For loss of consortium damages according to proof;

6. For exemplary or punitive damages according to proof;

7. For costs of suit herein;

8. For prejudgment interest on all damages as allowed by laws;

9. For injunctive relief, enjoining Defendants from the acts of unfair competition and untrue and misleading advertising;

10. For disgorgement of profits according to proof; and

11. For such other and further relief as the Court deems just and proper.

Dated: April 19, 2012

BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.

By: _____
Cynthia L. Garber, Esq.
Michael L. Baum, Esq.

Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues.

Dated: April 19, 2012

BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.

By: _____
Cynthia L. Garber, Esq.
Michael L. Baum, Esq.

Attorneys for Plaintiffs