UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS PRODUCTS LIABILITY LITIGATION **ALFRED GALLIER; and ANNE GALLIER;** **ROBERT RICHARDSON;** **RICHARD CARLOS; and KATHLEEN ANN CARLOS;** **JOHN SIMMONDS;** **Plaintiffs,** **vs.** **TAKEDA PHARMACEUTICALS AMERICA, INC.;** **TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.;** **TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.;** **TAKEDA PHARMACEUTICAL COMPANY LIMITED;** **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,** **Defendants**	**MDL No. 6:11-md-2299** **JUDGE DOHERTY** **MAGISTRATE JUDGE HANNA** **Civil Action No. 6:12-cv-02208** **BUNDLED COMPLAINT AND DEMAND FOR JURY TRIAL**

BUNDLED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs (1) ALFRED GALLIER; and ANNE GALLIER; (2) ROBERT RICHARDSON; (3) RICHARD CARLOS; and KATHLEEN ANN CARLOS; (4) JOHN

SIMMONDS; who by and through their counsel, bring this action against the Defendants Takeda Pharmaceuticals America, Inc. ("Takada America"), Takeda Pharmaceuticals North America, Inc. ("Takeda North America"), Takeda Pharmaceuticals International, Inc. ("Takeda International") Takeda Pharmaceutical Company Limited ("Takada Limited"), Takeda Pharmaceuticals, LLC ("Takeda LLC"), Takeda Global Research & Development Center, Inc. ("Takeda Global"), Takeda California, Inc., fka Takeda San Diego, Inc. ("Takeda California"), (collectively "Takeda" or "Defendants"), and Eli Lilly and Company ("Lilly" or "Defendants") and allege the following upon information and investigation of counsel:

INTRODUCTION

1. This action seeks to recover damages for injuries caused to Plaintiffs as the direct and proximate result of the wrongful conduct of the Defendants in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely used diabetes prescription drug Actos (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with Type 2 diabetes. Actos is sold as a single ingredient product under the brand name Actos.

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the Plaintiffs reside.

3. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. §1367.

4. Venue is proper in this District pursuant to 28 D.D.C. § 1391(a) because the Defendants marketed, advertised, and distributed the dangerous product in this Federal District,

and caused harm to the Plaintiffs who resided within this District. The Defendants do substantial business in the State of Louisiana, and within this Federal District, and at all times relevant hereto, the Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Actos in interstate commerce.

PARTIES

5. Plaintiff, ALFRED GALLIER, and his spouse, ANNE GALLIER are adult residents of the State of Texas, County of Nueces. Plaintiff, ALRED GALLIER, was prescribed Actos and did ingest Actos. Plaintiff, ALFRED GALLIER, has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

6. Plaintiff ROBERT RICHARDSON, is an adult resident of the State of Texas, County of Tarrant. Plaintiff ROBERT RICHARDSON, was prescribed Actos and did ingest Actos. Plaintiff ROBERT RICHARDSON, has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

7. Plaintiff, RICHARD CARLOS, and his spouse KATHLEEN ANN CARLOS are adult residents of the State of Nevada, County of Douglas. Plaintiff, RICHARD CARLOS, was prescribed Actos and did ingest Actos. Plaintiff, RICHARD CARLOS, has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

8. Plaintiff, JOHN SIMMONDS, is an adult resident of the State of California, County of El Dorado. Plaintiff, JOHN SIMMONDS, was prescribed Actos and did ingest Actos. Plaintiff, JOHN SIMMONDS, has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

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DEFENDANTS

9. Takeda America is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

10. Takeda America is a wholly owned subsidiary of Takeda North America.

11. Takeda America has transacted and conducted business throughout the United States and the State of Louisiana.

12. Takeda America has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Louisiana.

13. Takeda America expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

14. Takeda North America is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

15. Takeda North America is a wholly owned subsidiary of Takeda Limited.

16. Takeda North America has transacted and conducted business throughout the United States and the State of Louisiana.

17. Takeda North America has derived substantial revenue from goods and products disseminated throughout the United States and the State of Louisiana.

18. Takeda North America expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

19. Takeda International is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL, 60015.

20. Takeda International is a wholly owned subsidiary of Takeda Limited.

21. Takeda International has transacted and conducted business throughout the United States and the State of Louisiana.

22. Takeda International has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Louisiana.

23. Takeda International expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

24. Takeda Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka, 540-8645, Japan.

25. Takeda Limited is the parent company of Takeda North America, and Takeda America is a wholly owned subsidiary of Takeda North America.

26. Takeda Limited has transacted and conducted business throughout the United States and the State of Louisiana.

27. Takeda Limited has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Louisiana.

28. Takeda Limited expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

29. Takeda LLC is a Delaware limited liability company, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

30. Takeda LLC is a wholly owned subsidiary of Takeda Limited.

31. Takeda LLC has transacted and conducted business throughout the United States and the State of Louisiana.

32. Takeda LLC has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Louisiana.

33. Takeda LLC expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

34. Takeda Global is an Illinois corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois, 60015.

35. Takeda Global is a wholly owned subsidiary of Takeda Limited.

36. Takeda Global has transacted and conducted business throughout the United States and the State of Louisiana. At all relevant times alleged herein Takeda Global was involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

37. Takeda Global has derived substantial revenue from goods and products disseminated and used throughout the United States and the State of Louisiana.

38. Takeda Global expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

39. 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.

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

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

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

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

44. Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

45. Lilly has transacted and conducted business throughout the United States and the State of Louisiana.

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

47. Lilly expected or should have expected their acts to have consequences throughout the United States and the State of Louisiana, and derived substantial revenue from interstate commerce.

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

49. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from Plaintiffs, Plaintiffs' 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 more than twelve months of Actos ingestion.

50. As a result of Defendants' actions and inactions, Plaintiffs were injured due to ingestion of Actos, which caused injuries. Plaintiffs accordingly seek damages associated with these injuries.

FACTUAL ALLEGATIONS

51. 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.

52. 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.

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

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

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

56. 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.

57. 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.

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

59. 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.

60. 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,* Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

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

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

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 the 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 $mg/m^{2)}$." The present Actos label states: "There are too few events of bladder cancer to establish causality."

66. After the FDA approved Actos for marketing in the U.S., 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. On September 17, 2010, the FDA issued a Safety Announcement 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.

68. 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.

69. 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 has not shown a risk to patients of bladder cancer or other cancers from Actos.

70. 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 April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009.

71. 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.

72. 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."

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

74. 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.

75. 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.

76. 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.

77. 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 that were followed for 4 years (2006-2009).

78. On June 10, 2011, Reuters published 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.

79. 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 ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

80. Again, the FDA reported that the risk of bladder cancer increased with increasing dose 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.

81. On July 12, 2011, Takeda Limited issued a recall on Actos in France.

82. 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.

83. As the manufacturers of Actos, Defendants knew or should have known that Actos use for longer than twelve months was associated with bladder cancer.

84. With the knowledge of the true relationship between long-term use of Actos and developing bladder cancer, rather than take steps to pull the drug off the market, Defendants promoted Actos as a safe and effective treatment for Type 2 diabetes.

85. Despite its knowledge of this dangerous side effect that can result from Actos use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

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

87. In 2008, with the knowledge of the risk associated with developing bladder cancer while using Actos long term, 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.

88. Consumers, including Plaintiffs, 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 long-term Actos therapy.

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

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

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

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

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

94. As a direct result of being prescribed Actos for many years, Plaintiffs, have been permanently and severely injured, having suffered serious consequences, from long-term Actos use.

95. Plaintiffs, as a direct and proximate result of long-term Actos use, suffered serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, by reason of the foregoing, Plaintiffs

suffered economic losses and special damages including, but not limited to, loss of earnings, and medical expenses, all to the Plaintiffs' general and special damage in excess of the jurisdictional limits of the unlimited Court.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants and DOES 1 through 100)

96. 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.

97. 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.

98. 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.

99. 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 Plaintiffs.

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

101. Defendants' and DOES 1 through 100, and each of them, inclusive, their negligence and/or recklessness was a substantial factor and legal and proximate cause of Plaintiffs, injuries, physical pain and suffering, mental anguish, and loss of enjoyment of life.

102. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs suffered economic losses and special damages including, but not limited to, loss of earnings, and medical expenses, all to the Plaintiffs' general and special damage in excess of the jurisdictional limits of the unlimited Court.

103. In particular, Plaintiffs will 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 Plaintiffs' diseases, 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 as 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 Plaintiffs, Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof at trial.

104. 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.

105. 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 maintains and reserves 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)

106. 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.

107. 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 the Plaintiffs directly and Plaintiffs' physicians to warn of risks associated with the use of the Product.

108. 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.

109. 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 Plaintiffs, and Plaintiffs' physicians, and continued to aggressively promote Actos.

110. 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.

111. This use resulted in injury to Plaintiffs. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of Actos. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured Actos in such a way as to increase the risk of harm or injury to the recipients of Actos.

112. Actos is defective in design because of its propensity to cause bladder cancer and other indefinite injuries after discontinuation of use.

113. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Actos to Plaintiffs.

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

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

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

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

118. 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, Plaintiffs were caused to suffer from the aforementioned injuries, and damages.

119. 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 the injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their disease and injuries.

120. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs suffered severe and permanent injuries to their persons, and Plaintiffs suffered damages as alleged above.

121. In particular, Plaintiffs will 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 Plaintiffs' diseases, 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 as 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 Plaintiffs, such that Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

THIRD CAUSE OF ACTION

STRICT LIABILITY - DEFECTIVE DESIGN

(Against All Defendants and DOES 1 through 100)

122. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

123. Actos is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design.

124. At all times material to this action, Actos was expected to reach, and did reach, consumers in Plaintiffs' state of citizenship and throughout the United States, including Plaintiffs herein, without substantial change in the condition in which it was sold.

125. At all times material to this action, Actos was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Actos contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks that exceeded the benefits of the subject product, including, but not limited to permanent personal injuries including, but not limited to, developing bladder cancer and other serious injuries and side effects.

b. When placed in the stream of commerce, Actos was defective in design and formulation, making the use of Actos more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type II diabetes;

c. Actos' design defects existed before it left the control of the Defendants;

d. Actos was insufficiently tested;

e. Actos caused harmful side effect that outweighed any potential utility; and

f. Actos was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiffs herein, of the full nature and extent of the

risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

126. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiffs' injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiffs' injuries without substantially impairing the product's utility.

FOURTH CAUSE OF ACTION

MANUFACTURING DEFECT

(Against All Defendants and DOES 1 through 100)

127. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

128. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Actos.

129. At all times material to this action, Actos was expected to reach, and did reach, consumers in Plaintiffs' states of citizenship and throughout the United States, including Plaintiffs herein without substantial change in the condition in which it was sold.

130. At all times material to this action, Actos was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Actos contained manufacturing defects

which rendered the subject product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specification or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of the Defendants.

131. The subject product manufactured and/or supplied by Defendant was defective in construction or composition in that, when it left the hands of Defendant, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing bladder cancer. The product was unreasonably dangerous in construction or composition.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(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. 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.

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

135. 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. The subject product was unreasonably dangerous because it failed to conform to an expressed warranty of the defendant as provided by La.R.S.9:2800.58.

136. 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 Plaintiffs' health, and shrinking their life expectancy.

137. 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 Plaintiffs.

138. 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 Plaintiffs' injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their diseases and injuries.

139. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs suffered severe and permanent injuries to their person, and Plaintiffs suffered damages as alleged above in paragraphs 51 through 54.

140. In particular, Plaintiffs will 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 Plaintiffs' diseases 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 as 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 Plaintiffs, such that, Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

(Against All Defendants and DOES 1 through 100)

141. 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.

142. 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.

143. 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.

144. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiffs' health and shortened their life expectancy.

145. Plaintiffs relied on the implied warranty of fitness for a particular use and purpose.

146. Plaintiffs 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.

147. 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.

148. 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.

149. 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 Plaintiffs.

150. 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 the injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their diseases and injuries.

151. 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 the injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their diseases and injuries.

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

153. In particular, Plaintiffs will 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 Plaintiffs diseases 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 as 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 Plaintiffs such that Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants and DOES 1 through 100)

154. 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.

155. 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.

156. 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 Plaintiffs and impliedly warranted to Plaintiffs 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.

157. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiffs' health and shortened their life expectancy.

158. Plaintiffs 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.

159. 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.

160. 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 Plaintiffs.

161. 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 the injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their disease and injuries.

162. 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 the injuries and damages thereby sustained by Plaintiffs, 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 Plaintiffs, and such intentional acts and omissions were substantial factors in causing their disease and injuries.

163. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, inclusive, Plaintiffs suffered severe and permanent injuries to their person, and Plaintiffs suffered damages as alleged above.

164. In particular, Plaintiffs will 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 their diseases 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 as 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 Plaintiffs, such that Plaintiffs for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

EIGHTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA BUSINESS & PROFESSIONS

CODE §17200, et seq.

(Against All Defendants and DOES 1 through 100)

165. 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.

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

167. 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."

168. The acts and practices described in Paragraphs 1 through 95 above, were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of California 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 California Business & Professions Code §17200. This conduct includes, but is not limited to:

(a) Representing to Plaintiffs, Plaintiffs' 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 Plaintiffs,

Plaintiffs' 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 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.

169. 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.

170. 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.

171. Plaintiffs, pursuant to California Business & Professions Code §17203, 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 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.

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NINTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA BUSINESS & PROFESSIONS

CODE §17500, et seq.

(Against All Defendants and DOES 1 through 100)

172. 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.

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

174. 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.

175. 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 California 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 Plaintiffs, Plaintiffs' 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 Plaintiffs, Plaintiffs' 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.

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

177. 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.

178. 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.

179. Pursuant to California Business & Professions Code §17535, Plaintiffs 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. Plaintiffs seek the imposition of a constructive trust over, and restitution and disgorgement of, monies collected and profits realized by said Defendants, and each of them, and an order directing Defendants to cease such false and misleading advertising in the future.

TENTH CAUSE OF ACTION

DECEIT BY CONCEALMENT - CALIFORNIA *CIVIL CODE* §§1709, 1710

(Against All Defendants and DOES 1 through 100)

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

of this Complaint and further state as follows:

181. 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 Plaintiffs by concealing from the Plaintiffs, and Plaintiffs' health care providers and the general public, the true facts concerning Actos, which the Defendants had a duty to disclose.

182. 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 and willfully deceived Plaintiffs, and Plaintiffs' physicians and the general public by concealing that the health risks and consequences of the use of Actos and pioglitazone hydrochloride were hazardous to health, and that Actos and pioglitazone hydrochloride have a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Plaintiffs as described herein.

183. Defendants intentionally concealed and suppressed the true facts concerning the Actos and pioglitazone with the intent to defraud Plaintiffs, in that Defendants knew that Plaintiffs' physicians would not have prescribed Actos and pioglitazone hydrochloride and Plaintiffs would not have used Actos and pioglitazone hydrochloride if Plaintiffs had known the true facts concerning the dangers of Actos and pioglitazone hydrochloride.

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

ELEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(Against All Defendants and DOES 1 through 100)

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

186. Defendants, and each of them, from the time that Actos and pioglitazone hydrochloride was first tested, studied, researched, manufactured, marketed and distributed, and

up to the present, made false representations, as previously set forth herein, to Plaintiffs, and Plaintiffs' health care providers, and the general public including, but not limited to, the misrepresentation that Actos and pioglitazone hydrochloride was safe, fit, and effective for human consumption.

187. 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 and willfully deceive Plaintiffs, and Plaintiffs' health care providers, and the general public as to the health risks and consequences of the use of Actos and pioglitazone hydrochloride.

188. Defendants made the foregoing misrepresentations 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 Actos and pioglitazone hydrochloride.

189. The foregoing representations by Defendants, and each of them, were in fact false, in that Actos and pioglitazone hydrochloride is not, and at all relevant times alleged herein, was not safe, fit, and effective for human consumption, and that the use of Actos and pioglitazone hydrochloride is hazardous to health, and that Actos and pioglitazone hydrochloride 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 Actos and pioglitazone hydrochloride.

190. In reliance on the misrepresentations by Defendants, and each of them, Plaintiffs were induced to purchase and use Actos and pioglitazone hydrochloride. If Plaintiffs had known of the true facts concealed by Defendants, Plaintiffs would not have used Actos and pioglitazone hydrochloride. 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.

191. As a result of the foregoing negligent 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 Plaintiffs such that, Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

TWELFTH CAUSE OF ACTION

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

(Against All Defendants and DOES 1 through 100)

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

193. 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").

194. 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.

195. Plaintiffs are a "consumer" within the meaning of California Civil Code § 1761(d).

196. 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).

197. 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 Actos and pioglitazone hydrochloride:

(a) Representing to Plaintiffs, and Plaintiffs' 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 Plaintiffs, and Plaintiffs' 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.

198. 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.

199. 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.

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THIRTEENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(Against All Defendants and DOES 1 through 100)

200. 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.

201. Plaintiff ALFRED GALLIER, is legally married to Plaintiff ANNE GALLIER and, at all relevant times alleged herein the Plaintiffs were, and are, legally married to one another.

202. Plaintiff RICHARD CARLOS, is legally married to Plaintiff KATHLEEN ANN CARLOS and, at all relevant times alleged herein the Plaintiffs were, and are, legally married to one another.

203. As a direct and proximate result of the injuries and damages alleged herein, Plaintiffs were deprived of the comfort and enjoyment of the services and society of their legal spouse, and have suffered and will continue to suffer general and special damages including, but not limited to, economic loss, and have otherwise been emotionally and economically injured. The Plaintiffs' 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.

204. At all relevant times alleged herein Plaintiffs were and are the lawful spouses of Plaintiffs, and, as such, were and are entitled to the comfort, enjoyment, society and services of their spouses.

205. Plaintiffs sustained injuries caused by Actos and pioglitazone hydrochloride. Prior to the aforesaid injuries, Plaintiffs, were able to and did perform duties as a spouse to Plaintiffs.

206. Subsequent to the injuries, and as a proximate result thereof, Plaintiffs, were 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 have sustained special

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

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

208. 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 as 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 Plaintiffs, such that Plaintiffs, for the sake of example, and by way of punishing said Defendants, seek punitive damages according to proof.

FOURTEENTH CAUSE OF ACTION

REDHIBITION

(Against All Defendants and DOES 1 through 100)

209. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

210. Actos and pioglitazone hydrochloride contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

211. Defendants sold and promoted Actos and pioglitazone hydrochloride which Defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. Actos and pioglitazone hydrochloride, sold and promoted by Defendants, possess a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and for is

unreasonably dangerous, as described above, which renders Actos and pioglitazone hydrochloride useless or so inconvenient that it must be presumed that a buyer would not have bought Actos and pioglitazone hydrochloride had she known of the defect. Pursuant to La. C.C. art. 2520, Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

212. Actos and pioglitazone hydrochloride alternatively possess a redhibitory defect because Actos and pioglitazone hydrochloride was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of Actos and pioglitazone hydrochloride so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

213. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defects, and thus, are liable to Plaintiffs for the price of Actos and pioglitazone hydrochloride, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of Actos and pioglitazone hydrochloride and attorney's fees. As the manufacturer of Actos and pioglitazone hydrochloride, under Louisiana law, Defendants are deemed to know that Actos and pioglitazone hydrochloride possessed a redhibitory defect. La. C.C. art. 2545.

PRAYER FOR RELIEF

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

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

2. Past and future economic and special damages according to proof at the time of trial;

3. Loss of earnings and impaired earning capacity according to proof at the time of trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. For past and future mental and emotional distress, according to proof;

6. Punitive or exemplary damages according to proof at the time of trial;

7. Restitution and other equitable relief;

8. Injunctive relief;

9. Attorney's fees;

10. For costs of suit incurred herein;

11. For pre-judgment interest as provided by law; and

12. For such other and further relief as the Court may deem just and proper.

Dated: August 17, 2012

/s/ Cynthia L. Garber

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DEMAND FOR JURY TRIAL

Plaintiffs hereby request a trial by jury of all issues triable by jury.

Dated: August 17, 2012

/s/ Cynthia L. Garber

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