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IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

TIMOTHY PLAUGHER, an Individual; and PEGGY ANN PLAUGHER, an Individual,

Plaintiff(s),

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. 2299

Hon. Rebecca Doherty

CASE NO: 6:12:cv-709

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Timothy Plaugher and Peggy Ann Plaugher (alternatively referred to as "Plaintiffs"), residing in Winchester, Virginia by and through the undersigned attorneys, hereby bring this cause of action against Defendants:

Takeda Pharmaceuticals America, Inc. ("Takeda America");

Takeda Pharmaceuticals North America, Inc. ("Takeda North America");

Takeda Pharmaceuticals International, Inc. ("Takeda International");

Takeda Pharmaceutical Company Limited ("Takeda 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"); and

Eli Lilly and Company ("Lilly" or collectively with Takeda as "Defendants") and as for their Complaint allege, upon information and belief and based on the investigation to date of counsel, as follows:

INTRODUCTION

1. This is a personal injury action brought for injuries caused to Plaintiffs as a result of ingesting Defendants' unreasonably dangerous and defective 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 exceed $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 Plaintiff resides.

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 Court pursuant to 28 U.S.C. § 1391 because a substantial part of Defendants' business activities giving rise to Plaintiffs' claims occurred in the Southern District of Illinois.

PLAINTIFF

5. Plaintiff Timothy Plaugher, and his wife Peggy Ann Plaugher are citizens of Virginia, natural persons and residents of Winchester, Virginia.

6. Plaintiff Timothy Plaugher used the prescription Actos as prescribed and directed by his physician for long-term maintenance of Type 2 diabetes.

7. Plaintiff was injured as a result of his use of Actos, and therefore seeks damages, ascertainable economic losses, attorneys' fees, reimbursement of cost of obtaining Actos, reimbursement for all past, present, and future health and medical care costs related to Actos.

DEFENDANTS

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

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

10. Takeda America has transacted and conducted business throughout the United States and the State of Virginia.

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

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

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

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

15. Takeda North America has transacted and conducted business throughout the United States and the State of Virginia.

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

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

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

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

20. Takeda International has transacted and conducted business throughout the United States and the State of Virginia.

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

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

23. 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.

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

25. Takeda Limited has transacted and conducted business throughout the United States and the State of Virginia.

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

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

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

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

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

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

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

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

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

35. Takeda Global has transacted and conducted business throughout the United States and the State of Virginia. 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.

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

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

38. 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.

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

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

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

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

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

44. Lilly has transacted and conducted business throughout the United States and the State of Virginia.

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

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

47. From 2006 through February 2012, Plaintiff took Actos manufactured and distributed by Defendants for treatment of Type 2 diabetes.

48. 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.

49. 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 more than twelve months of Actos ingestion.

50. 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. Plaintiff accordingly seeks 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. 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.

58. 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.

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

60. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve months, including Plaintiff, were at increased risk for developing bladder cancer, have suffered and may continue to suffer from bladder cancer.

61. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve months, including Plaintiff, developed bladder cancer, have suffered and may continue to suffer from bladder cancer.

62. Defendants concealed their knowledge that Actos can cause bladder cancer from Plaintiff, other consumers, and the medical community.

63. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos for more than twelve months.

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

65. 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.

66. 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").

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

68. 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.

69. 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.

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

71. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of cancer in users of Actos to prevent any chances of its products' registrations being delayed or rejected by the FDA.

72. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

73. 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.

74. 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.

75. 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. 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."

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

86. 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.

87. 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.

88. 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.

89. 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 long-term Actos therapy.

90. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Actos use.

91. As a result of Defendants' actions, Plaintiff and his physicians were unaware, and could not have reasonably known or have 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.

92. In 2006, Plaintiff was prescribed and began taking Actos upon direction of his physician for long-term maintenance of Type 2 diabetes. Plaintiff subsequently developed bladder cancer in May 2010. Plaintiff ceased using Actos in February 2012.

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

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

95. Plaintiff, as a direct and proximate result of long-term 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.

96. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its long-term use.

FEDERAL REQUIREMENTS

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

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

99. 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 their 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, and/or (d) route or method of administration or application, 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, and/or (d) route or method of administration or application.

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 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos' cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k) 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.

1) 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 situations, and the Defendants failed to state such information.

m) 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.

n) 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.

o) 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.

p) The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug Actos.

q) 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.

r) 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.

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

t) 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.

u) 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.

v) 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.

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

x) 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.

y) 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.

z) 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.

aa) 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.

bb) 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.

cc) 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.”

dd) 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.

ee) 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).

ff) 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.

100. 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 Nevada law.

FIRST CAUSE OF ACTION
STRICT LIABILITY

101. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

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

103. The Actos products as distributed by Defendants were defective and unreasonably dangerous prescription drug products, as Defendant failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular — the common, foreseeable and intended use of Actos therapy as long-term maintenance for type II diabetes.

104. At all times relevant to this action, Defendants manufactured, supplied, and/or sold Actos in a defective and dangerous condition, as described above, to physicians, including Plaintiff's physician.

105. As a direct, foreseeable and proximate result of Defendants' defective Actos product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months).

106. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

107. At all times relevant to this action, Defendants were manufacturers of Actos.

108. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of

commerce Actos, in the course of same, directly advertised or marketed the product to health care professionals and consumers, including Plaintiff, or persons responsible for consumer, and therefore had a duty to warn of the risks associated with the use of Actos.

109. Defendants failed to adequately warn health care professionals and the public, including Plaintiff Timothy Plaugher and his prescribing physician, of the true risks of Actos, including that use of Actos for longer than twelve (12) months carried an increase risk in developing bladder cancer.

110. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Actos. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician would have prescribed Actos for prolonged periods, or no consumer, including Plaintiff, would have used Actos for a prolonged period of time.

111. Actos, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings because, after Defendants knew or should have known that there was reasonable evidence of an association between Actos and bladder cancer, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote Actos.

112. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

113. As a direct, foreseeable and proximate result of Defendants' breaches of their duties to exercise reasonable care for the safety of users of their respective products, by negligently failing to adequately test Actos and negligently failing to provide adequate warnings and instructions for same, to healthcare professionals and consumers, misleading Plaintiff, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above.

THIRD CAUSE OF ACTION

NEGLIGENT DESIGN DEFECT

114. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

115. Defendants are the researcher, developer, designer, manufacturer, distributor, marketer, promoted, supplier and seller of Actos, which is defective and unreasonably dangerous to consumers.

116. 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. Actos is defective in design or formulation in that it lacks efficacy and/or poses a greater likelihood of injury than other similar medications on the market and are more dangerous than ordinary consumers, including Plaintiff, can reasonably foresee.

117. If the design defect was known at the time of manufacture, a reasonable person would have concluded that the utility of Actos did not outweigh the risk of marketing a product designed in that manner.

118. The defective condition of Actos rendered it unreasonably dangerous and/or not reasonably safe and Actos was in the defective condition at the time it left the hands of the

Defendants. Actos was expected to, and did reach consumers, including Plaintiff, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

119. Plaintiff and his physician were unaware of the significant hazards and defects associated with Actos.

120. Actos was unreasonably safe and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used Actos, it was being utilized in a manner that was intended by Defendants.

121. At the time Plaintiff received and used Actos, it was represented to be safe and free from latent defects.

122. Defendants were negligent for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use at the time it left the control of Defendants because of design defects.

123. Defendants, as prescription drug manufacturers and/or distributors, knew or should have known of the dangers associated with the prolonged use of Actos as well as the defective nature of Actos, but continued to design, manufacture, sell, distribute, market, promote and/or supply Actos so as to maximize sales and profits at the expense of the public health and safety in conscious disregard of the foreseeable harm caused by Actos.

124. As a direct, foreseeable and proximate result of Defendants' breaches of their duties to exercise reasonable care for the safety of users of their respective products, by negligently failing to adequately test Actos and negligently failing to provide adequate warnings and instructions for same, to healthcare professionals and consumers, misleading Plaintiff,

Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above.

FOURTH CAUSE OF ACTION

NEGLIGENCE

125. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

126. As a manufacturer of a prescription pharmaceutical drug product, Defendants owed a duty toward foreseeable users of Actos, including Plaintiff, to exercise reasonable care to ensure that Actos products, as manufactured and/or distributed, were reasonably safe for their ordinary and intended uses and, specifically, to ensure through adequate testing, labeling, and otherwise, that physicians (and their patients) were adequately informed as to the potential effects and inherent risks of using Actos in an ordinary and foreseeable manner.

127. Defendants breached the duties they owed to exercise reasonable care for the safety of users of their products, including Plaintiff, by failing to exercise reasonable care in testing their products to identify all inherent risks and associated effects when used in an ordinary and foreseeable manner.

128. Defendants also breached the duties they owed to exercise reasonable care for the safety of users of their products, including Plaintiff, by negligently failing to disseminate, in a manner reasonably calculated to be seen and read by physicians (or their patients), information concerning their respective products' effects, which was accurate, not misleading, and otherwise adequate to enable physicians (or their patients) to make informed choices concerning the reasonably safe use of their products.

129. As a direct, foreseeable and proximate result of Defendants' breaches of their duties to exercise reasonable care for the safety of users of their respective products, by negligently failing to adequately test Actos and negligently failing to provide adequate warnings and instructions for same, to healthcare professionals and consumers, misleading Plaintiff, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above.

FIFTH CAUSE OF ACTION

NEGLIGENCE *PER SE*

130. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

131. As part of their duty to exercise reasonable care for the safety of persons, including Plaintiff, who would be expected to use their products, Defendants were obliged to follow public laws and regulations enacted and promulgated to protect the safety of such persons, including 21 U.S.C. 331(a) and 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

132. The package inserts (and other labeling, if any) for each of the Actos products failed to conform to the requirements of 21 U.S.C. §352, including subsections (a), (c), and (f), or the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), as the package inserts and/or other labeling failed to contain, *inter alia,* information, including warnings and instructions for use, adequate to enable the use of Actos in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use, or to bear "information for its use, including... any relevant hazards, contraindications, side effects, and precautions" that were adequate to

enable doctors to "use the drug safely and for the purposes for which it is intended"; and, in addition, contained false, inaccurate, and/or misleading statements concerning their respective products' side effects.

133. Accordingly, Defendants, in distributing the Actos products labeled in violation of these statutes and associated regulations, were negligent *per se*, that is, negligent as a matter of law.

134. As a direct, foreseeable and proximate result of the negligence *per se* of Defendants, specifically, their violations of the above-referenced statutes and regulations, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance on Defendants' compliance with these health and safety laws and regulations, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months. Plaintiff ingested Actos as prescribed and instructed by his physician, leading to his injuries.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

135. Plaintiff incorporates by reference each preceeding paragraph as though set forth fully at length herein.

136. The Actos product materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of the Actos products, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. Such failure by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Actos sold to Plaintiff.

137. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months. Plaintiff purchased and ingested Actos as prescribed and instructed by his physician, leading to his injuries.

138. Defendants impliedly warranted their respective Actos products, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the products were sold.

139. Defendants breached their implied warranties of the Actos products sold to Plaintiff because these products were not fit for their common, ordinary, and intended use.

140. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the implied warranties, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time exceeding twelve (12) months. Plaintiff purchased and ingested Actos as prescribed and instructed by his physician, leading to his injuries.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

141. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

142. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning Actos, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

143. Defendants disseminated to physicians, through published labels and otherwise, information concerning the properties and effects of Actos with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

144. Defendants, as prescription drug manufacturers and/or distributors, knew or reasonably should have realized that physicians, in weighing the potential benefits and potential risks of using Actos, would rely upon information disseminated to them by the manufacturer of the name brand product, and that many patients, in accordance with those prescriptions, would be likely to ingest Actos as properly dispensed by their pharmacies.

145. Defendants, as prescription drug manufacturers and/or distributors, knew or reasonably should have realized that patients receiving prescriptions for Actos, written by physicians in reliance upon information disseminated by Defendants as the manufacturer/distributor of Actos, would be placed in peril of grievous personal injury if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

146. Defendants failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Actos was accurate and not misleading, and, as a result, disseminated information to physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff.

147. As a direct, proximate and foreseeable result of Defendants' negligence, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when his physicians, in reasonable reliance upon the negligently inaccurate, misleading, and otherwise false information disseminated by Defendants, and believing the information to be true, prescribed for Plaintiff the use of Actos for a prolonged and unwarranted period of time, exceeding twelve (12) months. Plaintiff ingested Actos as prescribed and instructed by his physician, leading to his injuries.

NINTH CAUSE OF ACTION

VIOLATION OF CONSUMER PROTECTION LAWS

148. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

149. Plaintiff purchased and used Actos primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

150. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

a) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

151. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety and effectiveness of Actos.

152. Defendants uniformly communicated the purported benefits of Actos while failing to disclose the serious and dangerous side-effects related to Actos and of the true state of Actos, the regulatory status, its safety, its efficacy and its true usefulness. Defendants made these representations to physicians, the medical community at large and to patients and consumers, such as Plaintiff, in their marketing and advertising.

153. Defendants' conduct in connection with Actos was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding (among other things) the utility, benefits, costs, safety, efficacy and advantages of Actos.

154. As a result of the aforesaid statutory violations, Plaintiffs are entitled to relief, as prayed for below.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

155. Plaintiff(s) incorporate by reference each preceding paragraph as though set forth fully at length herein and further alleges as follows.

156. Plaintiff, Peggy Ann Plaugher, was at all times relevant hereto the spouse of Plaintiff Timothy Plaugher, and as such lives and cohabitates with him.

157. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

158. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society and the ability of Plaintiff's spouse, have in those respects, been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, Plaintiff has been caused great mental anguish.

PUNITIVE DAMAGES

159. Defendant's conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including the Plaintiff, by suppressing the knowledge of the safety and efficacy problem from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, as follows:

a. Awarding monetary damages to Plaintiffs for all of Plaintiffs' injuries in an amount to be determined at trial, as alleged herein;

b. Awarding pre-judgment and post-judgment interest to Plaintiffs;

c. Awarding the costs and the expenses of this litigation to Plaintiffs;

d. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law; and

e. Granting all such other relief as the Court deems necessary, just and proper.

Dated: March 20, 2012

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

By: /s/ Cynthia L. Garber
Cynthia L. Garber, Esq.
Michael L. Baum, Esq.

Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

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

Dated: March 20, 2012

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

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

Attorneys for Plaintiffs