UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS PRODUCT LIABILITY LITIGATION	)	**MDL No. 6:11-md-2299**
	)	**JUDGE DOHERTY**
ROBERT RAYMOND, individually and as Administrator of the Estate of Joseph Raymond, Sr., deceased	)	**MAGISTRATE JUDGE HANNA**
Plaintiff,	)	
vs.	)	**Civil Action No.:_____**
TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS, LLC; TAKEDA SAN DIEGO, INC.; and ELI LILLY AND COMPANY,	)	
Defendants.	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Robert Raymond ("Robert" or "plaintiff"), Administrator of the Estate of Joseph Raymond ("decedent"), by and through the undersigned attorneys, hereby brings this cause of action against Defendants Takeda Pharmaceuticals America, Inc., ("Takeda America"), Takeda Pharmaceuticals North America, Inc. ("Takeda North America"), Takeda Global Research & Development Center, Inc. ("Takeda Global Research"), Takeda Pharmaceutical Company Limited ("Takeda Limited"), Takeda Pharmaceuticals International, Inc. ("Takeda International"), Takeda Pharmaceuticals, LLC ("Takeda Pharmaceuticals"), Takeda San Diego, Inc. ("Takeda San Diego") (collectively "Takeda") and Eli Lilly and Company ("Lilly" or

collectively with Takeda as "Defendants") and as for his Complaint alleges 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 and death caused to Joseph Raymond, 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.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to the Plaintiff exceeds $75,000, 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 resided.

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 Plaintiff's claims occurred in Virginia.

PLAINTIFFS

5. Plaintiff, Robert Raymond, individually and on behalf of the Estate of Joseph Raymond, deceased, is a natural person and a citizen and resident of Georgia. Plaintiff Robert Raymond brings a survival action on behalf of the Estate of Joseph Raymond and brings a wrongful death on behalf of the Estate of Joseph Raymond. Decedent Joseph Raymond was a natural person and a citizen and resident of Virginia. Decedent Joseph Raymond ingested the

prescription drug Actos between approximately 2002 and 2010 as prescribed and directed by his physician and was injured and suffered bladder cancer and death as a result of his use of Actos.

6. Joseph Raymond was injured and died as a result of his use of Actos, and therefore Robert Raymond, as Administrator of Joseph Raymond's Estate, seeks damages for Joseph Raymond's pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement of costs of obtaining Actos, reimbursement for all past, present, medical care costs related to Actos and for Joseph Raymond's death, caused by ingestion of Actos.

DEFENDANTS

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

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

9. Takeda America has transacted and conducted business within the State of Virginia.

10. Takeda America has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

11. Takeda America expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

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

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

14. Takeda North America has transacted and conducted business within the State of Virginia.

15. Takeda North America has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

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

17. Takeda Global Research is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

18. Takeda Global Research is a wholly owned subsidiary of Takeda North America.

19. Takeda Global Research has transacted and conducted business within the State of Virginia.

20. Takeda Global Research has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

21. Takeda Global Research expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

22. 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.

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

24. Takeda Limited has transacted and conducted business within the State of Virginia.

25. Takeda Limited has derived substantial revenue from goods and products disseminated and used in the State of Virginia .

26. Takeda Limited expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

27. Takeda Pharmaceuticals International, Inc. is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

28. Takeda Pharmaceuticals International, Inc. is a wholly owned subsidiary of Takeda North America.

29. Takeda Pharmaceuticals International, Inc. has transacted and conducted business within the State of Virginia.

30. Takeda Pharmaceuticals International, Inc. has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

31. Takeda Pharmaceuticals International, Inc. expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

32. Takeda Pharmaceuticals, LLC is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

33. Takeda Pharmaceuticals, LLC is a wholly owned subsidiary of Takeda North America.

34. Takeda Pharmaceuticals, LLC has transacted and conducted business within the State of Virginia.

35. Takeda Pharmaceuticals, LLC has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

36. Takeda Pharmaceuticals, LLC expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

37. Takeda San Diego, Inc. is a Delaware corporation which has its principal place of business at 10410 Science Center Drive, San Diego, CA 92121.

38. Takeda San Diego, Inc. is a wholly owned subsidiary of Takeda North America.

39. Takeda San Diego, Inc. has transacted and conducted business within the State of Virginia.

40. Takeda San Diego, Inc. has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

41. Takeda San Diego, Inc. expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

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

43. Lilly has transacted and conducted business within the State of Virginia.

44. Lilly has derived substantial revenue from goods and products disseminated and used in the State of Virginia.

45. Lilly expected or should have expected their acts to have consequences within the State of Virginia, and derived substantial revenue from interstate commerce.

SUMMARY OF THE CASE

46. From approximately 2002 through February 2010, Joseph Raymond took Actos, manufactured and distributed by Defendants for treatment of Type 2 diabetes.

47. As a result of the defective nature of Actos, persons who were prescribed and who subsequently ingested this product, including Joseph Raymond, have suffered from bladder cancer.

48. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from Joseph Raymond, his physician(s), 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.

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

FACTUAL ALLEGATIONS

50. 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.

51. 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.

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

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

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

55. 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.

56. Takeda Limited described this partnership as "a great success" and "mutually beneficial to both companies."

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

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

61. Defendants concealed their knowledge that Actos can cause bladder cancer from Joseph Raymond, other consumers, and the medical community.

62. 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.

63. As a result of Defendants' actions and inactions, Joseph Raymond was injured due to his ingestion of Actos, which caused Joseph Raymond various injuries and damages. Robert Raymond accordingly seeks damages associated with these injuries.

64. As a result of Defendants' actions and inactions, Joseph Raymond died due to his ingestion of Actos. Robert Raymond 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 (**PRO**spective Pioglit**A**zone **C**linical **T**rial **I**n Macro**V**ascular **E**vents) 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, 266:1279-1289 (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 will 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 that the agency 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 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 *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. 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 ("EMA") 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, exposed 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. Piccini, *et al.* analyzed the association between anti-diabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System ("AERS") 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 Joseph Raymond, 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 Joseph Raymond and his physician(s) the true and significant risks associated with long-term Actos use.

91. As a result of Defendants' actions, Joseph Raymond and his physician(s) were unaware, and could not have reasonably known or have learned through reasonable diligence, that Joseph Raymond 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 or around 2002, Joseph Raymond was prescribed and began taking Actos upon direction of his physician(s) for long-term maintenance of Type 2 diabetes. Joseph Raymond ceased using Actos in or around March 2010. Joseph Raymond subsequently was diagnosed with bladder cancer and died as a result thereof.

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

94. Plaintiff, as a direct and proximate result of long-term Actos use, suffered severe mental and physical pain and suffering and sustained permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses.

95. Joseph Raymond would not have used Actos had Defendants properly disclosed the risks associated with its long-term use.

FEDERAL REQUIREMENTS

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

97. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et. seq.*

98. With respect to the prescription drug Actos, the Defendants, upon information and belief, has 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's 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 §2 01.5, 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, 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.

l. 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 after significantly more 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 does, 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 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 and 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 §2 10.122 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 followup."

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.

99. 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 Joseph Raymond, making the Defendants negligent under Virginia law (i.e., negligent per se).

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

100. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with Actos and pioglitazone hydrochloride.

101. As a result of Defendants' actions, Joseph Raymond and Joseph Raymond's prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

102. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of Actos and pioglitazone hydrochloride. Defendants were under a duty to disclose the true character, quality and nature of Actos because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Joseph Raymond, his medical providers and/or to his health facilities.

103. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Joseph Raymond and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

104. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

105. Defendants had a duty to Joseph Raymond to exercise reasonable care in 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.

106. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, 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.

107. Despite the fact that Defendants knew or should have known that Actos was associated with and/or caused bladder cancer, Defendants continued to market, manufacture, distribute and/or sell Actos to consumers, including the Joseph Raymond.

108. Defendants knew or should have known that consumers such as Joseph Raymond would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

109. Defendants' negligence and/or recklessness was the proximate cause of Joseph Raymond's injuries, harm and economic loss which he suffered.

110. As a result of Defendants' negligence and/or recklessness Joseph Raymond was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries.

111. As a result of the foregoing acts and omissions Joseph Raymond required health care services and did incur medical, health, incidental and related expenses.

112. By reason of the foregoing, Robert Raymond demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

113. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

114. Defendants 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 the same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both Joseph Raymond directly and Joseph Raymond's physician(s) to warn of risks associated with the use of the product.

115. Defendants 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.

116. The Actos and pioglitazone hydrochloride manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings and/or instructions

because, after the 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 Joseph Raymond and Joseph Raymond's physician(s), and continued to aggressively promote Actos.

117. 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.

118. Defendants failed to adequately warn Joseph Raymond and Joseph Raymond's prescribing physician(s) of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

119. Had Joseph Raymond been adequately warned of the potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Joseph Raymond would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

120. Upon information and belief, had Joseph Raymond's prescribing physician(s) been adequately warn of potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Joseph Raymond's prescribing physician(s) would have discussed the risks of bladder cancer and Actos with Joseph Raymond and/or would not have prescribed it.

121. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Joseph Raymond was caused to suffer from the aforementioned injuries and damages.

122. By reason of the foregoing, Robert Raymond demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of

$75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN)

123. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

124. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

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

126. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actions.

127. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers it was unreasonably dangerous and was also more dangerous than the ordinary customer would expect.

128. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants knew and had reason to know that the

product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by the Defendants.

129. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

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

131. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced a defective product that caused an unreasonable risk to the health of consumers, and to Joseph Raymond in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Joseph Raymond.

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

133. Joseph Raymond could not, in the reasonable exercise of care, have discovered Actos' defects and perceived its danger.

134. The defects in Defendants' product were substantial and contributing factors in causing Joseph Raymond's injuries and death.

135. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Joseph Raymond was caused to suffer from the aforementioned injuries, death, and damages.

136. Due to the unreasonably dangerous condition of Actos, Defendants are strictly liable to Plaintiff.

137. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FOURTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

138. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

139. Defendants 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.

140. The express warranties represented by the Defendants were a part of the basis for Plaintiff's use of Actos and Joseph Raymond relied on these warranties in deciding to use Actos.

141. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the Actos and pioglitazone hydrochloride was to be used, and warrantied the same to be in all respects safe, effective, and proper for such purpose.

142. 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 Joseph Raymond's health, and ultimately his death.

143. As a result of the foregoing breach of express warranty Joseph Raymond was caused to suffer bladder cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, any and all life complications caused by Plaintiff's bladder cancer, as well as death.

144. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

FIFTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE)

145. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

146. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

147. The Defendants 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.

148. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Joseph Raymond's health, and ultimately caused his death.

149. Joseph Raymond relied on the implied warranty of fitness for a particular use and purpose.

150. Joseph Raymond reasonably relied upon the skill and judgment of Defendants as to whether Actos was safe and fit for its intended use.

151. Actos and pioglitazone hydrochloride were injected into the stream of commerce by the Defendants 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.

152. Defendants breached the aforesaid implied warranty, as their drug Actos was not fit for its intended purposes and uses.

153. As a result of the foregoing breach of warranty, Joseph Raymond was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and death.

154. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

155. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

156. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold Actos and pioglitazone hydrochloride to treat Type 2 Diabetes Mellitus.

157. Defendants marketed, sold, and distributed Actos and knew and promoted the use for which Actos was being used by Joseph Raymond and impliedly warranted to Joseph Raymond 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.

158. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Joseph Raymond's health, and ultimately caused his death.

159. Joseph Raymond reasonably relied on the skill, expertise, and judgment of the Defendants and its representations as to the fact that Actos was of merchantable quality.

160. The Actos and pioglitazone hydrochloride manufactured and supplied by the Defendants 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 which it was intended.

161. As a direct and proximate result of the foregoing, Joseph Raymond was caused bodily injury, pain and suffering, economic loss, and death.

162. As a result of the foregoing acts and omissions, Joseph Raymond was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including death.

163. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

164. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

SEVENTH CAUSE OF ACTION
(NEGLIGENCE *PER SE*)

165. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

166. 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.

167. 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.

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

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

EIGHTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

170. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

171. 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.

172. 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.

173. 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.

174. 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.

175. 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 Joseph Raymond.

176. As a direct, proximate, and foreseeable result of Defendants' negligence, Joseph Raymond suffered grievous bodily injury and consequent economic and other loss, as described above, when his physician(s), in reasonable reliance upon the negligently inaccurate, misleading,

and otherwise false information disseminated by Defendants, and believing the information to be true, prescribed for Joseph Raymond the use of Actos for a prolonged and unwarranted period of time, exceeding twelve months. Joseph Raymond ingested Actos as prescribed and instructed by his physician(s), leading to his injuries.

PUNITIVE DAMAGES

177. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

178. Defendants' conduct, as described above, was extreme, outrageous, oppressive, fraudulent, and/or malicious. Defendants risked the lives of consumers and users of their products, including Joseph Raymond, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

a. For past medical and incidental expenses, according to proof;

b. For past and future loss of earnings and/or earning capacity, according to proof;

c. For past and future general damages, according to proof;

d. For punitive and exemplary damages in an amount to be determined at trial;

e. For pre-judgment and post-judgment interest;

f. For the costs of this action, including reasonable attorneys' fees; and

g. Granting any and all such other and further relief as the Court deems necessary, just, and proper.

Respectfully submitted this 30th day of July 2012.

Respectfully submitted,

/s/ Michael L. McGlamry
Michael L. McGlamry
Georgia Bar No. 492515

/s/ N. Kirkland Pope
N. Kirkland Pope
Georgia Bar No. 584255

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efile@pmkm.com

(Attorneys for Plaintiff(s))

DEMAND FOR JURY TRIAL

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

DATED: July 30, 2012

Respectfully submitted,

/s/ Michael L. McGlamry
Michael L. McGlamry
Georgia Bar No. 492515

/s/ N. Kirkland Pope
N. Kirkland Pope
Georgia Bar No. 584255

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(Attorneys for Plaintiff(s)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

ROBERT RAYMOND, individually and as Administrator of the Estate of Joseph Raymond, Sr., deceased

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Pope, McGlamry, Kilpatrick, Morrison & Norwood, P.c.
3455 Peachtree Road, N.E., Suite 925
(404)-524-1648

DEFENDANTS

Takeda Pharmaceuticals America, Inc., et. al.,

County of Residence of First Listed Defendant Lake County, Illinois
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Pharmaceutical Personal Injury/Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Doherty DOCKET NUMBER 6:11-md-2299

DATE 7/30/12

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE