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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS (PIOGLITAZONE) PRODUCTS LIABILITY LITIGATION	MDL NO. 6:11-md-2299 JUDGE DOHERTY MAGISTRATE JUDGE HANNA
This Document Applies To: KATHLEEN GREGORIA, Individually, and as Administratrix of the Estate of RONALD J. GREGORIA, deceased Plaintiff, -against- TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, and ELI LILLY and COMPANY, Defendants.	Civil Index No.: 6:12-cv-00394 **AMENDED COMPLAINT WITH WRONGFUL DEATH CLAIM AND DEMAND FOR JURY TRIAL**

Plaintiff Kathleen Gregoria, Individually, and as Administratrix of the Estate of Ronald Gregoria, deceased, through her attorneys, Lynch Daskal Emery LLP, as and for her Amended Complaint with Wrongful Death Claim and Demand for Jury Trial against defendants, alleges as follows:

1. This is a personal injury and wrongful death action brought for injuries caused to plaintiff's decedent Ronald J. Gregoria 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 mellitus. Significantly, Actos has been linked to bladder cancer and the defendants knew or should have known of the risk and failed to adequately warn plaintiff's decedent causing severe bodily injuries and harm. Defendants concealed the dangers of Actos and other important safety information and caused plaintiff's decedent to suffer from bladder cancer and suffer injuries and damages

PARTIES

2. Plaintiff's decedent Ronald J. Gregoria ("plaintiff") died on July 15, 2013. He previously resided at 82 Vermillion Lane, Levittown, Pennsylvania 19054.

3. Plaintiff Kathleen Gregoria was the lawful wife of Mr. Gregoria and resided with him at 82 Vermillion Lane, Levittown, Pennsylvania 19054. She was granted Letters Administration of the Estate of Ronald J. Gregoria by the Register of Wills of Bucks County, Pennsylvania on August 9, 2013.

4. Defendant Takeda Pharmaceuticals North America Inc. ("Takeda North America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda Pharmaceuticals North

America Inc. is involved in the research, development, sales and marketing of pharmaceutical products, including Actos and pioglitazone hydrochloride.

5. Defendant Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois. Upon information and belief, Takeda America is a wholly owned subsidiary of Takeda North America.

6. Defendant Takeda Global Research and Development Center, Inc. ("Takeda Global Research") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois. Upon information and belief, Takeda Global Research is a wholly owned subsidiary of Takeda North America.

7. Defendant Takeda Pharmaceutical Company Limited ("Takeda Limited") is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. As part of its business, Takeda Limited is involved in the research, development, sales, and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride. Upon information and belief, Takeda Limited is a wholly owned subsidiary of Takeda North America.

8. Defendant Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Starting in 1999, Takeda North America and Lilly collaborated in the United States to promote and market Actos.

SUBJECT MATTER JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because complete diversity exists among the parties.

10. All defendants have substantial contacts with and receive benefits and income from and through the State of Louisiana, and derived substantial revenue from interstate commerce. This includes selling, marketing and distributing their products including Actos and pioglitazone hydrochloride in Louisiana.

11. Venue is proper within this District pursuant to the First General Order dated January 23, 2012 in MDL No. 6:11-md-2299 (RFD)(PJH), which allowed direct filing of Actos actions in this District.

SUMMARY OF THE CASE

12. From approximately 2005 to 2008, plaintiff's decedent Ronald Gregoria took Actos, which is manufactured and distributed by defendants for treatment of Type 2 diabetes.

13. As a result of the defective nature of Actos, persons who were prescribed and who subsequently ingested the product, including plaintiff's decedent, have suffered and will continue to suffer from bladder cancer.

14. Plaintiff's decedent Ronald Gregoria was initially diagnosed with bladder cancer on or about June 27, 2007. A subsequent cystoscopy taken on or about September 21, 2007 revealed a high grade muscle invasive bladder cancer.

15. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from plaintiff's decedent, his physicians, other consumers, and the medical community. Specifically, defendants failed to adequately inform consumers and the

prescribing medical community about the risks of bladder cancer associated with Actos ingestion.

16. As a result of defendants' actions and inactions, plaintiff's decedent was permanently and severly injured, having suffered serious consequences from long-term Actos use, including wrongful death. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

17. At all relevant times, defendants directly or through their agents, servants, and employees designed, researched, manufactured, marketed, sold, and distributed Actos and pioglitazone hydrochloride for the treatment of Type 2 diabetes mellitus.

18. 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. Insulin is necessary for the body to be able to use glucose for energy.

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

20. Actos received FDA approval in 1999 to treat Type 2 diabetes mellitus.

21. On July 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.

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

23. Prior to applying for and obtaining approval for Actos, defendants were in possession of pre-clinical scientific studies, including human and animal evidence, and

defendants knew or should have known that the use of Actos in humans was associated with and/or would cause the induction of bladder cancer.

24. Despite bladder cancer findings in animal model carcinogenicity studies and other pre-clinical evidence, defendants failed to adequately conduct complete and proper testing of Actos prior to filing its New Drug Application of Actos.

25. From the date of approval to market Actos, defendants made, distributed, marketed and sold Actos without adequate warning to plaintiff's decedent or plaintiff's decedent's physicians that Actos was associated with and/or could cause bladder cancer and presented a risk of bladder cancer in patients who used it and without adequate warning that defendants had not adequately conducted complete and proper testing and studies of Actos with regard to carcinogenicity.

26. For over 10 years to date, defendants concealed and failed to completely disclose their knowledge that Actos was associated with or could cause bladder cancer. Defendants also failed to disclose their knowledge that they did not fully study and test that risk.

27. Defendants' failure to disclose information that they possessed regarding the failure to adequately study and test Actos for bladder cancer risk further rendered warnings for this medication inadequate.

28. Upon information and belief, defendants ignored the association between the use of Actos and pioglitazone hydrochloride and the risk of developing bladder cancer.

29. On June 7, 2011, the Caisse nationale de l'assurance maladie, at the request of the French regulatory agency, published a report concluding that there is a statistically significant association between exposure to pioglitazone (Actos) and bladder cancer and that the risk increased with exposure longer than one year.

30. On June 9, 2011, the European Medicine Agency suspended the use of Actos in light of the French Marketing Authorization Committee and the French National Pharmacovigilance Committee's findings regarding the increased risk of bladder cancer.

31. On June 10, 2011, Germany's Federal Institute for Drugs and Medical Devices suspended the use of Actos.

32. On June 15, 2011, the FDA informed the public that use of the diabetes medication Actos for more than one year may be associated with an increased risk of bladder cancer.

33. The Actos label was then changed to reflect this information in the Warnings and Precautions section as well as the patient Medication Guide to include information regarding the risk of bladder cancer.

34. On June 17, 2011, Health Canada Press Release indicated that in light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada informed healthcare professionals and Canadians that it is undertaking a review of the drug's status.

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

36. As a proximate result of defendants' conduct, plaintiff's decedent Ronald Gregoria's physician prescribed Actos to Mr. Gregoria and Mr. Gregoria used Actos from approximately 2005 through 2008.

37. As a result of using defendants' Actos, plaintiff's decedent Ronald Gregoria was caused to suffer bodily injury in 2007 and thereafter including cancerous tumor(s) in his bladder and was thus caused to suffer severe and permanent personal injuries, pain, suffering, and mental anguish. He subsequently died on July 15, 2013.

38. The injuries, damages, and wrongful death suffered by plaintiff's decedent was caused or substantially contributed by defendants' Actos and the defendants' wrongful conduct.

39. The product warnings for Actos in effect during the time period plaintiff's decedent used Actos were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as plaintiff's decedent of the bladder cancer risk associated with this drug.

40. Defendants did not provide adequate warnings to plaintiff's decedent's doctors, plaintiff, the health care community, and the general public about the increased risk of serious adverse events that are described herein.

41. Consumers, including plaintiff's decedent, who have used Actos for treatment of Type 2 diabetes, have several alternative safer products available to treat the conditions.

42. Plaintiff's decedent would not have used Actos had defendants properly disclosed the life-threatening risks associated with it and would have chosen to request other treatments or prescription medications.

43. Defendants, through their affirmative misrepresentations and omissions, actively concealed from plaintiff's decedent and his physicians the true and significant risks associated with Actos use. The running of any applicable statute of limitations has been tolled by reason of defendants' fraudulent concealement.

44. As a result of defendants' actions, plaintiff's decedent and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that plaintiff's decedent had been exposed to the risks identified in the Complaint, and that those risks were the direct and proximate result of defendants' acts, omissions, and misrepresentations.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Negligence – Failure to Warn/Design Defect)

45. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

46. 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.

47. Defendants had a duty to plaintiff's decendent and his physicians to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Actos and pioglitazone hydrochloride into the stream of commerce, including a duty to assure that Actos and pioglitazone hydrochloride would not cause users to suffer unreasonable, dangerous side effects such as cancer.

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

49. 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 and physicians, including plaintiff's decedent.

50. Defendants refused to warn consumers, physicians and the medical community about the risk of bladder cancer.

51. Actos and pioglitazone hydrochloride was defectively designed in that it was reasonably certain to be dangerous when used in a reasonably foreseeable manner, including the manner that was directed on the package.

52. There are safer, available alternative medications for Type 2 diabetes mellitus.

53. The benefit of the use of Actos and pioglitazone hydrochloride for Type 2 diabetes mellitus is outweighed by the risk of serious injury, including bladder cancer.

54. It would have been feasible to design Actos and pioglitazone in a way that would have eliminated or substantially diminished the risk of bladder cancer and other dangers and health risks.

55. Defendants knew or should have known that consumers such as the plaintiff's decedent would foreseeably suffer injury as a result of defendants' failure to exercise ordinary care, as set forth above.

56. Defendants breached their duty of reasonable care owed to plaintiff's decedent and his physicians to design Actos and pioglitazone in a reasonably safe manner and to warn of the dangers of bladder cancer and other dangers and health risks.

57. As a direct and proximate consequence of defendants' acts, omissions, negligence and/or recklessness, plaintiff's decedent 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, a risk of future cancer, reasonable fear of future cancer, and all life complications caused by plaintiff's decedent's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

58. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Strict Liability – Design Defect)

59. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

60. 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.

61. At all relevant times, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by plaintiff's decedent.

62. It would have been feasible to design Actos in a way that would have eliminated or substantially diminished the risk of bladder cancer and other dangers and health risks. This is demonstrated by the existence of other Type 2 diabetes mellitus medications which have a more established safety profile and a considerably lower risk profile.

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

64. Defendants' sale of a defective product to plaintiff's decedent was a substantial and contributing factor in causing Mr. Gregoria injuries, including bladder cancer and a dramatic degradation in the quality of his life.

65. Due to the unreasonably dangerous condition of Actos, defendants are strictly liable to plaintiff.

66. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Strict Liability – Failure to Warn)

67. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

68. 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 same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers.

69. Defendants knew or had reason to know adverse drug reactions could be caused by the use of Actos and pioglitazone hydrochloride and/or are associated with the use of Actos and pioglitazone hydrochloride.

70. The Actos and pioglitazone hydrochloride manufactured and/or supplied by 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 the use of Actos, defendants failed to provide adequate warnings of the product, including to plaintiff's decedent and his physicians, and continued to aggressively promote Actos.

71. 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.

72. Defendants failed to adequately warn plaintiff's decedent and his physicians of human and animal results in pre-clinical studies pertaining to bladder cancer and Actos.

73. Defendants' failure to adequately warn plaintiff's decedent and his physicians of a bladder cancer risk prevented his prescribing physicians and plaintiff's decedent from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

74. Defendants' sale of a defective product to plaintiff's decedent was a substantial and contributing factor in causing plaintiff's decedent's injuries, including bladder cancer and a dramatic degradation in the quality of his life.

75. Due to the unreasonably dangerous condition of Actos and pioglitazone hydrochloride, defendants are strictly liable to plaintiff.

76. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Breach of Express Warranty)

77. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

78. Defendants expressly warranted that Actos and pioglitazone hydrochloride were safe and did not conform to 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, and that it would improve health, maintain health, and potentially prolong life.

79. The express warranties represented by the defendants were a part of the basis for plaintiff's decedent's use of Actos and plaintiff's decedent relied on these warranties in deciding to use Actos.

80. 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 warranted same to be in all respects safe, effective and proper for such purpose.

81. Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side-effects, including among other things, bladder cancer, degrading plaintiff's decedent's health, and reducing his life expectancy.

82. As a direct and proximate result of defendants' breach of their express warranties, plaintiff's decedent suffered severe injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life.

83. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Breach of Implied Warranty for a Particular Purpose)

84. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

85. Defendants impliedly represented and warranted to the users of Actos that Actos and pioglitazone hydrochloride were safe and fit for a particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

86. These representations and warranties were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride was unsafe, degraded plaintiff's decedent's health and reduced his life expectancy.

87. Plaintiff's decedent relied on the implied warranty of fitness for a particular use and purpose.

88. Plaintiff's decedent reasonably relied upon the skill and judgment of defendants as to whether Actos was safe and fit for its intended use.

89. 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 expanded 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.

90. Defendants breached the implied warranty of fitness for a particular use and purpose, as their drug Actos was not fit for its intended purposes and uses.

91. As a direct and proximate result of defendants' breach of their express warranties, plaintiff's decedent suffered severe injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life.

92. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Breach of Implied Warranty of Merchantability)

93. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

94. Defendants marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by plaintiff's decedent and impliedly warranted to plaintiff that Actos was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

95. These representations and warranties were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded plaintiff's decedent's health and reduced his life expectancy.

96. Plaintiff's decedent relied on the skill, expertise and judgment of the defendants and their representatives as to the fact that Actos was of merchantable quality.

97. The Actos and pioglitazone hydrochloride manufactured and supplied by the defendants were not of merchantable quality because the drug has dangerous and life threatening side effects and is not fit for the ordinary purpose for which it is intended.

98. As a direct and proximate result of defendants' breach of their implied warranties, plaintiff's decedent suffered severe injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life.

99. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Fraud and Deceit)

100. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

101. As set forth above, defendants fraudulently represented to physicians, the public, and plaintiff's decedent that using Actos for Type 2 mellitus diabetes was safe when, in fact, it was not.

102. Defendants fraudulently concealed and failed to advise plaintiff's decedent and his physicians of needed information regarding the use of Actos and of the health risks and hazards associated with Actos, including bladder cancer.

103. Defendants made the above-described representations with no reasonable grounds for believing them. Defendants did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care in ascertaining the accuracy of the information.

104. In representations to plaintiff's decedent, his physicians, and/or the Food and Drug Administration, defendants fraudulently concealed and intentionally omitted the following material information:

a. that Actos was not safe;

b. that the risks of adverse events with Actos were high;

c. that the risks of adverse events with Actos were not adequately tested and/or known by the defendants;

d. that defendants were aware of dangers in Actos, in addition to and above and beyond those associated with alternative medications;

e. that Actos was defective, and that it caused dangerous side effects; and

f. that patients needed to be monitored more regularly than normal while using Actos.

105. Defendants' material misrepresentations and omissions were knowingly and recklessly false and were made with the intent of inducing the public, medical community, and plaintiff's decedent into prescribing, purchasing, and using Actos for Type 2 diabetes mellitus.

106. These misrepresentations or omissions were made to the plaintiff's decedent, his physicians, and the medical community, all of whom justifiably and foreseeably relied on them.

107. As a direct and proximate result of defendants' fraudulent representations and misrepresentations, plaintiff's decedent suffered severe injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life.

108. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of plaintiff's decedent's damages. Plaintiff's decedent would not have suffered injuries but for the misrepresentations or omissions of defendants.

109. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Negligent Misrepresentation)

110. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

111. Defendants represented to the medical and healthcare community, and to the plaintiff, the FDA, and the public that Actos had been tested and found to be a safe and effective form of therapy.

112. Defendants material misrepresentations and omissions to plaintiff's decedent, the FDA, his physicians, and the public, caused defendants to breach their duty of reasonable care owed to plaintiff's decedent and his physicians to give accurate and adequate information regarding Actos and not to misrepresent or conceal any dangers regarding Actos known to them or which in the use of reasonable care they should have known.

113. Through the use of reasonable care, neither plaintiff's decedent nor his physicians could have discovered defendants' breach nor realized the danger of using or prescribing Actos.

114. As a direct and proximate result of defendants' misrepresentations, omissions, recklessness, negligence, and breaches of duty, plaintiff's decedent suffered severe injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life.

115. Plaintiff is entitled to punitive damages because defendants' conduct was wanton, grossly reckless, and/or in conscious disregard of plaintiff's decedent's rights and the other users of Actos and pioglitazone hydrochloride.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

NINTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Pennsylvania Unfair Trade Practices and Consumer Protection Law)

116. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

117. Plaintiff's decedent was prescribed and purchased Actos.

118. Plaintiff used Actos for its intended or reasonably foreseeable purpose, as a medication for Type 2 diabetes mellitus, in the manner directed by the product.

119. As set forth above, defendants deceptively and knowingly failed to provide needed, accurate, and adequate warnings and information regarding the health risks and hazards of Actos and pioglitazone hydrochloride to consumers, such as plaintiff's decedent, who would reasonably and foreseeably use the product and would be misled by such fraudulent and deceptive acts.

120. As a direct and proximate result of defendants' unconscionable commercial practice, including knowing concealment and fraudulent misrepresentations, plaintiff's decedent suffered injuries and damages, including bladder cancer and a dramatic degradation in the quality of his life. He also suffered ascertainable losses, in that plaintiff's decedent paid money to purchase Actos.

121. The foregoing knowing concealment and fraudulent misrepresentation by defendants constituted a violation of section 3 of the Unfair Trade Practices and Consumer Protection Law, entitling plaintiff to recover attorneys' fees and statutory damages.

TENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(Loss of Consortium)

122. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

123. At all times relevant to this Complaint, Mr. Gregoria's wife suffered damages as the result of the loss of Mr. Gregoria's services, society, and consortium.

124. As a direct and proximate result of defendants' conduct and the defective, unsafe, and unreasonably dangerous condition of Actos, Mr. Gregoria's wife was deprived of the services, society, and consortium of her husband.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

ELEVENTH CAUSE OF ACTION
AS AND AGAINST DEFENDANTS
(Wrongful Death Claim Pursuant to 42 Pa.C.S.A. § 8301 *et seq*.)

125. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

126. Plaintiff Kathleen Gregoria has the right to bring the following Wrongful Death Action on behalf of the wrongful death beneficiaries under the Pennsylvania Wrongful Death Statute, 42 Pa.C.S.A. § 8301, and pursuant to Pa.R.C.P. 2202(a).

127. Plaintiff's decedent died as a result of defects in Actos and is survived by various family members.

128. Defendants' wrongful conduct has proximately caused plaintiff's decedent's heirs to suffer the loss of plaintiff's decedent's companionship, services, society, marital association, love, and/or consortium. As a direct and proximate result of plaintiff's decedent's diseases, injuries, and death, his survivors have further sustained mental pain and suffering, mental anguish, grief, loss of capacity to lead a normal life, funeral expenses and expenses of medical care, nursing care and/or hospitalization to treat his condition. Such damages, injuries and losses are permanent and continuing in nature.

129. The persons entitled by law to recover wrongful death damages as a result of the death of plaintiff's decedent, are:

a. Kathleen Gregoria (82 Vermillion Lane, Levittown, PA 19054);

b. Michael J. Gregoria (1404 Highland Avenue, Parkland, PA 19047);

c. Karen A. Heitz (82 Vermillion Lane, Levittown, PA 19054); and

d. Mark R. Gregoria (12131 Barbary Road, Philadelphia, PA 19151).

130. As a direct and proximate result of plaintiff's decedent's diseases, injuries, and death, his survivors have lost the support and services of him, and have sustained the cost of funeral expenses and/or the cost of medical care, nursing care and/or hospitalization.

131. The administrator of plaintiff's decedent's estate brings this claim on behalf of the plaintiff's decedent's lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

132. In addition, plaintiff demands payment for all economic losses suffered by the plaintiff's decedent's survivors including costs of administration and other expenses reasonably associated with the plaintiff's decedent's death.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

TWELFTH CAUSE OF ACTION
AS AND AGAINST DEFENDANTS
(Survival Action 42 Pa.C.S.A. 8302)

133. Plaintiff repeats and realleges each and every allegation set forth above with the same force and effect as if set forth fully herein.

134. Plaintiff Kathleen Gregoria has the right to bring the following survival action on behalf of the estate of plaintiff's decedent under the Pennsylvania Survival Statute, 42 Pa.C.S.A. § 8302, and pursuant to 20 Pa.C.S.A. § 3373.

135. As a direct and proximate result of the defendants' wrongful conduct as outline above, plaintiff's decedent suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to plaintiff's decedent's death.

136. The untimely death of Ronald Gregoria on July 15, 2013 was caused by the intentional and negligent conduct of the defendants.

137. Plaintiff claims damages for the additional medical expenses incurred for the treatment of the plaintiff's decedent prior to his death along with the loss of his net earnings from the date of death until the respective remainder of his life and further claims all damages recoverable under the Pennsylvania Survival Statute.

138. Plaintiff claims on behalf of the estate of plaintiff's decedent all damages suffered by the estate by reason of the death of the plaintiff's decedent, as well as for pain and suffering and fear of impending death the plaintiff's decedent experienced prior to his death.

139. Plaintiff claims all other damages recoverable under the Pennsylvania Survival Statute.

WHEREFORE, 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 reasonable attorneys' fees, costs, and such other and further relief as may be deemed just and proper.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment against the defendants on each of the above-referenced claims and causes of action and as follows:

1. Awarding compensatory damages to plaintiff for past and future damages, including but not limited to irreparable body injury, including death; great pain of body and mind up until the time of his death; great embarrassment and humiliation up until the time of his death; permanent impairment to plaintiff's decedent earnings capacity up until the time of his death; the loss of enjoyment of life up until the time of his death, as well as, health costs, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the plaintiffs in an amount sufficient to punish defendants and deter future similar conduct;

3. Awarding plaintiff's attorney's fees;

4. Awarding the plaintiff the cost of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

DESIGNATION OF TRIAL AND LEAD COUNSEL

Bernard Daskal and Scott A. Harford are hereby designated as the plaintiff's trial and lead counsel.

Dated: September 24, 2013
New York, New York

Respectfully submitted,

/s/ Bernard Daskal
Bernard Daskal
/s/ Scott A. Harford
Scott A. Harford
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Attorneys for Plaintiff Kathleen Gregoria, Individually, and as Administratrix of the Estate of Ronald J. Gregoria

CERTIFICATE OF SERVICE

I, Bernard Daskal, hereby certify that on September 24, 2013, I electronically filed the Amended Complaint with Wrongful Death Claim and Jury Demand with the Clerk of the United States District Court for the Western District of Louisiana using the ECF system, which will send notification of such filing to registered ECF participants in this case.

Dated: New York, New York
September 24, 2013

Respectfully submitted,

/s/ Bernard Daskal
Bernard Daskal
/s/ Scott A. Harford
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