UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS PRODUCTS LIABILITY LITIGATION **EDWENE D. PERSON, individually and on behalf of JAMES PERSON, deceased; JOSE E. ASTORGA, individually and on behalf of PABLO ASTORGA,** **Plaintiffs,** **vs.** **TAKEDA PHARMACEUTICALS AMERICA, INC.;** **TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.;** **TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.;** **TAKEDA PHARMACEUTICAL COMPANY LIMITED;** **TAKEDA PHARMACEUTICALS, LLC.;** **TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.;** **TAKEDA CALIFORNIA, INC., fka TAKEDA SAN DIEGO, INC.;** **ELI LILLY AND COMPANY; and DOES 1 through 100, inclusive,** **Defendants.**	**MDL No. 6:11-md-2299** **JUDGE DOHERTY** **MAGISTRATE JUDGE HANNA** **Civil Action No._____** **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff EDWENE D. PERSON, individually and as Personal Representative of the Estate of JAMES PERSON, deceased; Plaintiff JOSE E. ASTORGA, individually and as successor in interest to PABLO ASTORGA, deceased, for causes of action

against Defendants and DOES 1 through 100, and each of them, who file this Complaint and allege as follows:

INTRODUCTION

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

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

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

4. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because the Defendants marketed, advertised, and distributed the dangerous product in this Federal District, and caused harm to the Plaintiffs who resided within this District. The Defendants do substantial business in the State of Louisiana, and within this Federal District, and at all times relevant hereto, the Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Actos in interstate commerce.

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PARTIES

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

6. Edwene D. Person is a surviving heir, Personal Representative and spouse of the deceased James Person (hereinafter "Decedent").

7. Plaintiff Edwene Person is a resident and citizen of the United States and currently resides in Gwinnett County, Georgia.

8. Jose E. Astorga is a surviving heir, successor in interest and son of the deceased Pablo Astorga (hereinafter "Decedent").

9. Plaintiff Jose E. Astorga is a resident and citizen of the United States and currently resides in Stanislaus County, California.

10. Plaintiffs are individuals that sustained damages and injuries as a result of injuries suffered by Decedents, damages incurred by Decedents and the deaths of Decedents, all caused by the prescription drug Actos and pioglitazone hydrochloride. Plaintiffs are authorized to bring this action against Defendants and DOES 1 through 100, inclusive, and each of them, who are responsible for the prescription drug Actos and pioglitazone hydrochloride, a diabetes medication used by Decedents that caused Decedents to suffer physical injuries and damages including, but not limited to, bladder cancer, related sequelae, pain and suffering, bodily impairment, mental anguish, diminished enjoyment of life, economic loss, other special damages and deaths.

DEFENDANTS

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

Illinois, 60015. At all relevant times alleged herein, TAKEDA PHARMACEUTICALS AMERICA, INC., was involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

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

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

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

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

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

17. Defendant TAKEDA CALIFORNIA, INC., formerly known as TAKEDA SAN DIEGO, INC., is a Delaware corporation with its principal place of business at 10410 Science Center Drive, San Diego, California 92121. At all relevant times alleged herein TAKEDA CALIFORNIA, INC., and its predecessor companies were involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

18. ELI LILLY AND COMPANY (hereinafter "LILLY") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

19. LILLY has transacted and conducted business in the United States of America, including the states of Georgia, California, and Louisiana, has derived substantial revenue from goods and products used in these states, has derived substantial revenue from interstate commerce, and LILLY expected, or should have expected, its acts to have consequences within the states of Georgia, California, and Louisiana.

20. Upon information and belief, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a company domiciled in Japan and is the parent/holding company of Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS, LLC.,

TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., and TAKEDA CALIFORNIA, fka TAKEDA SAN DIEGO.

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

22. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, and each of them, are unknown to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs and Decedents as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiffs for the acts and omissions alleged herein below, and the resulting injuries to Plaintiffs and Decedents, and damages sustained by the Plaintiffs and Decedents. Plaintiffs will amend this Complaint to allege the true names and capacities of said DOE Defendants when that same is ascertained.

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

24. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendants and DOES 1 through 100, inclusive, and each of them, were also known as,

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

25. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, that Defendants and DOES 1 through 100, inclusive, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said Defendants and DOE Defendants were and are authorized to do and are doing business in the United States of America, including the states of Georgia, California, and Louisiana, and regularly conducted business in these states.

26. Upon information and belief, at relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, were engaged in the business of researching, developing,

designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce in the United States of America, including the states of Georgia, California, and Louisiana, either directly or indirectly through third parties or related entities, its products, including Actos and pioglitazone hydrochloride.

27. At all relevant times, Defendants DOES 1 through 100, inclusive, and each of them, conducted regular and sustained business and engaged in substantial commerce and business activity in the United States of America, including the states of Georgia, California, and Louisiana, which included but was not limited to selling, marketing and distributing its products including Actos and pioglitazone hydrochloride.

28. At all relevant times, Defendants and DOES 1 through 100, inclusive, and each of them, expected or should have expected that their acts would have consequences within the United States of America, including the states of Georgia, California, and Louisiana, and said Defendants derived and derive substantial revenue therefrom.

29. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED expected or should have expected that its acts would have consequences in the United States of America, including the states of Georgia, California, and Louisiana, and said Defendant derived and derive substantial revenue from interstate commerce.

30. Upon information and belief, at all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED have transacted and conducted business in the United States of America, including the states of Georgia, California, and Louisiana, and/or contracted to supply goods and services within these states, and committed tortious acts within and without the states of Georgia, California, and Louisiana, causing injury out of which act(s) these causes of action arise.

FACTUAL BACKGROUND

31. At all relevant times, Defendants and DOES 1 through 100, and each of them, inclusive, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, Actos and pioglitazone hydrochloride for treatment of Type 2 Diabetes Mellitus.

32. Upon information and belief, Actos received FDA approval in 1999 to treat Type 2 Diabetes Mellitus and was jointly launched by TAKEDA entities and LILLY in the United States in 1999.

33. Upon information and belief, The TAKEDA Defendants described Actos as a "great success" and "mutually beneficial" to both companies – LILLY and TAKEDA - in public statements and press releases.

34. Prior to applying for and obtaining approval for Actos, Defendants and DOES 1 through 100, and each of them, inclusive, knew or should have known that Actos use in humans was associated with and/or would cause the induction of bladder cancer and said Defendants possessed pre-clinical scientific studies including animal evidence, which evidence said Defendants knew or should have known was a signal that bladder cancer risk needed to be further tested and studied before placing Actos on the market.

35. Despite bladder cancer findings in animal model carcinogenicity studies and other pre-clinical evidence, Defendants and DOES 1 through 100, and each of them, inclusive, failed to adequately conduct complete and proper testing of Actos prior to filing its New Drug Application of Actos.

36. It is now known that additional bladder cancer evidence from human clinical trials also became known to Defendants and DOES 1 through 100, and each of them, inclusive, in the early 2000's.

37. From the date of approval to market Actos, Defendants and DOES 1 through 100, and each of them, inclusive, made, distributed, marketed and sold Actos without adequate warning to Decedents' prescribing physicians or Decedents 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 said Defendants had not adequately conducted complete and proper testing and studies of Actos with regard to carcinogenicity.

38. For over 10 years and to date, Defendants and DOES 1 through 100, and each of them, inclusive, concealed and failed to completely disclose their knowledge that Actos was associated with or could cause bladder cancer or their knowledge that they had failed to fully study and test regarding that risk and, further, made conscious decisions to ignore the association between the use of Actos and pioglitazone hydrochloride and the risk of developing bladder cancer.

39. By the Defendants' and DOES 1 through 100, and each of their, inclusive, 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.

40. 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.

41. 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.

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

43. 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. 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.

44. FDA further recommended on June 15, 2011 that healthcare physicians discontinue pioglitazone use in patients with active bladder cancer.

45. 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.

46. Plaintiffs are informed and believe and based thereon allege that as a direct and proximate result of Decedents' use of the ACTOS PRODUCT, supplied and distributed by Defendants herein, Decedents suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to bladder cancer, bladder surgery, bladder failure other permanent physical deficits, permanent bodily impairment and other sequelae, ultimately resulting in Decedents' deaths. Decedents' injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damages caused by Decedents' use of the ACTOS PRODUCT as prescribed.

47. As a direct and proximate result of the wrongful conduct, acts, omissions, fraudulent misrepresentations, fraudulent business practices by Defendants and DOES 1 through 100, inclusive, Decedents' physicians prescribed Actos to said Decedents, Decedents used Actos as prescribed, Decedents were diagnosed with bladder cancer, Decedents died as a result of

bladder cancer and consequently Plaintiffs will be forever deprived of love, companionship, comfort, support, affection, society, solace and moral support of the Decedents.

48. As a result of using Defendants' product Actos, Decedents were caused to suffer continuous bodily injury including cancerous tumor(s) in the bladder that spread to other organs of Decedents' bodies, thus causing Decedents' to sustain severe and permanent personal injuries, pain, suffering, mental anguish, medical expenses, special damages and, finally, deaths.

49. As a further direct and proximate result of defects in Actos (hereinafter sometimes referred to as the "PRODUCT") and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiffs and Decedents suffered severe mental and physical pain and also incurred substantial medical expenses, funeral expenses and other economic harm in the form of loss of earnings and support as well as general damages including loss society, comfort and support.

50. As a further direct and proximate result of defects in the PRODUCT and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Decedents required extensive emergency medical treatment, health care, attention and services, thereby incurring medical, incidental, and service expenses pertaining to emergency medical treatments and procedures undertaken in efforts to save Decedents.

51. As a further direct and proximate result of defects in the PRODUCTS and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, the Decedents sustained fatal injuries, causing Plaintiffs to be forever deprived of love, companionship, comfort, support, affection, society, solace and moral support by Decedents, and thus causing Plaintiffs to sustain both economic and noneconomic damages.

52. Plaintiffs are individuals who suffered damages as a result of fatal injuries to Decedents resulting from Decedents' use of Actos and are authorized to bring an action for the

causes of action alleged herein including, but not limited to, wrongful deaths and survival, for the injuries and damages sustained by Decedents and Decedents' estates resulting from Decedents' use of Actos. Said injuries and damages sustained by Plaintiffs and Decedents were caused or substantially contributed to by the wrongful conduct of Defendants and DOES 1 through 100, inclusive.

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

54. The Defendants and DOES 1 through 100, and each of them, inclusive, did not provide adequate warnings to Decedents' doctors, Decedents, the health care community and the general public about the increased risk of serious adverse events that are described herein.

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

56. By reason of the foregoing, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death. By reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but not limited to, loss of earnings, medical expenses and funeral expenses. All to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

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FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants and DOES 1 through 100)

57. Plaintiffs incorporate by reference, each and every paragraph of this Complaint as if fully set forth herein and further allege as follows:

58. At all relevant times, Defendants had a duty to Plaintiffs and Decedents to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale and distribution of Actos, including a duty to ensure that Actos did not pose a significantly increased risk of persistent and/or permanent injury to its users.

59. Defendants had a duty to exercise reasonable care in the advertising and sale of Actos, including a duty to warn Decedents and other consumers, of the dangers associated with the consumption of Actos that were known or should have been known to Defendants at the time of the sale of Actos to Decedents.

60. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Actos because Defendants knew or should have known that Actos had a propensity to cause serious injury, including bladder cancer.

61. Defendants failed to exercise ordinary care in the labeling of Actos and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, without limitation, bladder cancer.

62. Defendants knew or should have known that Decedents and Plaintiffs could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

63. Defendants breached their duty of reasonable care to Plaintiffs and Decedents by failing to exercise due care under the circumstances.

64. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale and distribution of Actos, Decedents ingested Actos and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, treatments for depression, emotional distress, anxiety, for which Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION

STRICT LIABILITY - FAILURE TO WARN

(Against All Defendants and DOES 1 through 100)

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

66. Defendants and DOES 1 through 100, and each of them, researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Actos into the stream of commerce, and in the course of same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both the Decedents directly and Decedents' physicians to warn of risks associated with the use of this product.

67. Defendants and DOES 1 through 100, and each of them, 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.

68. The Actos and pioglitazone hydrochloride manufactured and/or supplied by the Defendants and DOES 1 through 100, and each of them, was defective due to inadequate post-

marketing warnings and/or instructions because, after the said Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Decedents and Decedents' physicians, and continued to aggressively promote Actos.

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

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

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

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

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

74. Defendants' failure to adequately warn Decedents and Decedents' prescribing physicians of a bladder cancer risk prevented Decedents' prescribing physicians and Decedents from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

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

76. Upon information and belief, had Decedents' prescribing physicians been adequately warned of the potential life-threatening side effects of Actos and pioglitazone hydrochloride, Decedents' prescribing physicians would have discussed the risks of bladder cancer and Actos with the Decedents and/or would not have prescribed it.

77. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants and DOES 1 through 100, and each of them, Plaintiffs and Decedents were caused to suffer from the aforementioned injuries, damages and untimely deaths.

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

79. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

80. As alleged here in this cause of action and throughout this Complaint, such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, were substantial factors in causing Decedents' diseases, injuries, deaths as well as the Plaintiffs' resulting damages. As the above referenced conduct complained of in this Complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Decedents, such that Plaintiffs, for the sake of example and by way of punishing said Defendants, seek punitive damages according to proof at trial.

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

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

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THIRD CAUSE OF ACTION

DEFECTIVE DESIGN

(Against All Defendants and DOES 1 through 100)

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

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

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

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

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

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

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

d. Actos was insufficiently tested;

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

f. Actos was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Decedents herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs and Decedents.

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

FOURTH CAUSE OF ACTION

MANUFACTURING DEFECT

(Against All Defendants and DOES 1 through 100)

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

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

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

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

a. When placed in the stream of commerce, Actos contained manufacturing defects which rendered the subject product unreasonably dangerous;
b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;
c. The subject product was not made in accordance with the Defendants' specification or performance standards; and
d. The subject product's manufacturing defects existed before it left the control of the Defendants.

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

but not limited to, developing bladder cancer. The product was unreasonably dangerous in construction or composition.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants and DOES 1 through 100)

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

94. Defendants and DOES 1 through 100, and each of them, 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.

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

96. At the time of the making of the express warranties, the Defendants and DOES 1 through 100, and each of them, 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.

97. Defendants and DOES 1 through 100, and each of them, breached the above-described express warranty in that Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among

other things bladder cancer, degrading Decedents' health, and thereby resulting in Decedents' deaths.

98. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, as described in this cause of action was a substantial factor and legal and proximate cause of the injuries and damages sustained by Plaintiffs and Decedents, and that said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiffs and Decedents, and that such intentional acts and omissions were substantial factors in causing the injuries and damages alleged herein.

99. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

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

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

(Against All Defendants and DOES 1 through 100)

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

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

103. The Defendants and DOES 1 through 100, and each of them, 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.

104. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Decedents' health and resulted in Decedents' deaths.

105. Decedents relied on the implied warranty of fitness for a particular use and purpose.

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

107. Actos and pioglitazone hydrochloride were injected into the stream of commerce by the Defendants and DOES 1 through 100, and each of them, 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.

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

109. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, were substantial factors and legal and proximate causes of the injuries and damages thereby sustained by Plaintiffs and Decedents, and that said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiffs and Decedents, and that such intentional acts and omissions were substantial factors in causing the injuries and damages alleged herein.

110. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

111. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but

not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

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

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants and DOES 1 through 100)

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

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

115. Defendants and DOES 1 through 100, and each of them, marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by Decedents and impliedly warranted to Decedents 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.

116. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Decedents' health and resulted in Decedents' deaths.

117. Decedents and Decedents' physicians reasonably relied on the skill, expertise and judgment of the Defendants and DOES 1 through 100, and each of their, and its representations as to the fact that Actos was of merchantable quality.

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

119. The breaches of warranty by Defendants and DOES 1 through 100, and each of them, as described in this cause of action were substantial factors and legal and proximate causes of the injuries and damages sustained by Plaintiffs and Decedents, and that said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiffs and Decedents, and that such intentional acts and omissions were substantial factors in causing the injuries and damages alleged herein.

120. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

121. As alleged here in this cause of action and throughout this Complaint, such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, were substantial factors in causing Decedents' diseases, injuries, deaths as well as the Plaintiffs' and Decedents' resulting damages. As the above referenced conduct complained of in this Complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiffs, and Decedents such that Plaintiffs, for the sake of example and by way of punishing said Defendants, seek punitive damages according to proof at trial.

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

EIGHTH CAUSE OF ACTION

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

(Against All Defendants and DOES 1 through 100)

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

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

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

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

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

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

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

127. As a result of their conduct described above Defendants and DOES 1 through 100, and each of them, have been and will be unjustly enriched. Specifically, said Defendants have been unjustly enriched by receipt of billions of dollars in ill-gotten gains from the sale and

prescription of said drugs in the United States of America, including Georgia, California, and Louisiana, sold in large part as a result of the acts and omissions described herein.

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

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

NINTH CAUSE OF ACTION

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

(Against All Defendants and DOES 1 through 100)

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

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

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

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

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

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

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

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

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

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

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

TENTH CAUSE OF ACTION

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

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

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

140. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of Actos and pioglitazone hydrochloride (hereinafter

"PRODUCT") and willfully deceived Decedents, Decedents' physicians and the general public as to the health risks and consequences of the use of the PRODUCT was hazardous to health, and that the PRODUCT has a significant propensity to cause serious injuries to users including, but not limited to, the injuries and damages suffered by Plaintiffs and Decedents as described herein.

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

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

ELEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

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

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

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

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

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

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

149. As a foreseeable, direct and proximate result of the aforesaid conduct of Defendants and DOES 1 through 100, and each of them, Decedents developed serious and dangerous side effects including bladder cancer, related sequelae, physical pain and suffering, mental anguish, loss of enjoyment of life and, finally, a very painful death and, by reason of the foregoing, Plaintiffs and Decedents suffered economic losses and special damages including, but

not limited to, loss of earnings, medical expenses and funeral expenses, all to the Plaintiffs' general and special damages in excess of the jurisdictional limits of the unlimited Court.

150. As alleged here in this cause of action and throughout this Complaint, such intentional, grossly wanton acts and omissions by Defendants and DOES 1 through 100, and each of them, were substantial factors in causing Decedents' disease, injuries, deaths as well as the Plaintiffs' resulting damages. As the above referenced conduct complained of in this Complaint of said Defendants was and is vile, base, willful, malicious, oppressive, and outrageous, and said Defendants demonstrated such an entire want of care as to establish that their acts and omissions were the result of actual conscious indifference to the rights, safety, and welfare of Plaintiffs, and Decedents such that Plaintiffs, for the sake of example and by way of punishing said Defendants, seek punitive damages according to proof at trial.

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

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

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

TWELFTH CAUSE OF ACTION

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

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

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

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

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

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

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

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

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

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

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

161. Unless Defendants are enjoined from continuing to engage in these violations of the CLRA, Plaintiffs and Decedents and other consumers will continue to be harmed by the wrongful actions and conduct of Defendants.

162. Pursuant to California Civil Code § 1780, Plaintiffs seek an order of this court for injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices in the future.

THIRTEENTH CAUSE OF ACTION

WRONGFUL DEATH

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

164. Plaintiffs are the surviving heirs of, Personal Representative and/or successor in interest to Decedents and are authorized to bring an action for the wrongful deaths of the Decedents, who used the PRODUCT and were injured and died as a result. Decedents were prescribed, supplied with, received, took, ingested, used and consumed said PRODUCT as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants herein.

165. The injuries and damages suffered by Plaintiffs and Decedents were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants.

166. As a result of Defendants' conduct, acts, omissions and practices as alleged herein, Decedents ingested the PRODUCTS and suffered fatal injuries.

167. As a result of the deaths of the Decedents, Plaintiffs were deprived of love, companionship, comfort, support, affection, society, solace and moral support of the Decedents.

168. Plaintiffs are entitled to recover economic and non-economic damages against all Defendants for wrongful deaths directly and legally caused by the defects in Defendants' PRODUCT and the negligent conduct, acts, errors, omissions and intentional and negligent misrepresentations of Defendants.

FOURTEENTH CAUSE OF ACTION

SURVIVAL ACTION

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

170. As a direct and proximate result of defects in the PRODUCT and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Decedents sustained the injuries and damages described herein.

171. As a further direct and proximate result of defects in the PRODUCT and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Decedents incurred special damages, in the form of the reasonable value of services rendered for medical care for the injuries that Decedents sustained prior to deaths. Plaintiffs are the personal representatives or successors in interest of the estates of the Decedents and are authorized to bring this survival action pursuant to California Code of Civil Procedure §§ 377.20 and 377.30, et seq, and other relevant law.

172. As a further direct and proximate result of defects in the PRODUCT and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiffs incurred special damages including, inter alia, funeral and burial expenses. Plaintiffs are the personal representatives or successors in interest of the estates of the Decedents and are authorized to bring this survival action pursuant to California Code of Civil Procedure §§ 377.20 and 377.30, et seq, and other relevant law.

173. The acts, conduct, practices and omissions of Defendants, and each of them, as alleged throughout this Complaint were fraudulent, willful and malicious and were undertaken with a conscious disregard for the rights of Plaintiffs and Decedents as well as other users of the PRODUCT, and were undertaken for the primary purpose of increasing Defendants' profits from the sale and distribution of the PRODUCT. Said outrageous and unconscionable conduct by Defendants warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant. Plaintiffs are the personal representatives or successors in interest of the estates of Decedents and are authorized to bring this survival action pursuant to California Code of Civil Procedure §§ 377.20 and 377.30, et seq. and other relevant law, and are thereby entitled to recover punitive damages against Defendants herein.

FIFTEENTH CAUSE OF ACTION

REDHIBITION

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

175. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

176. Defendants sold and promoted Actos, which Defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product, sold and promoted by Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and for is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had they known of the defect. Pursuant to La. C.C. art. 2520, Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, as follows:

1. Awarding monetary damages to Plaintiffs for all of Decedents' injuries in an amount to be determined at trial, as alleged herein;
2. Awarding pre-judgment and post-judgment interest to Plaintiffs;
3. Loss of earnings and impaired earning capacity according to proof at the time of trial;
4. Medical expenses, past and future, according to proof at time of trial;
5. For past and future mental and emotional distress, according to proof;
6. Punitive or exemplary damages according to proof at the time of trial;
7. Restitution and other equitable relief;
8. Injunctive relief; and
9. Attorney's fees.

Dated: September 14, 2012

/s/ Cynthia L. Garber
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DEMAND FOR JURY TRIAL

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

Dated: September 14, 2012

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