UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

JAY ROSENBLUM AND ROBIN REHDERS, Plaintiffs, v. TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and ELI LILLY AND COMPANY, Defendants. .	C.A. No.: **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs JAY ROSENBLUM and ROBIN REHDERS by and through their attorneys NAPOLI SHKOLNIK, LLC, bring this action for personal injuries suffered as a proximate result of JAY ROSENBLUM being prescribed and ingesting the defective and unreasonably dangerous drug Actos™ (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with Type II diabetes. Actos, at all times relevant hereto, was manufactured designed, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein.

PARTIES

1. At all times relevant hereto, Plaintiff JAY ROSENBLUM was a resident and citizen of the State of Florida. Plaintiff ROBIN REHDERS was also a resident and citizen of the State of Florida at all relevant times. At all relevant times, both were residents of Lakewood Ranch, Florida.

2. Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

3. Takeda America is a wholly owned subsidiary of Takeda U.S.A.

4. Takeda Pharmaceuticals U.S.A., Inc. f/k/a Takeda North America, Inc. ("Takeda U.S.A.") is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

5. Takeda U.S.A. is a wholly owned subsidiary of Takeda Limited.

6. Takeda Pharmaceutical Company Limited ("Takeda Limited") is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka, 540-8645, Japan.

7. Takeda Limited is the parent company of Takeda U.S.A., and Takeda America is a wholly owned subsidiary of Takeda U.S.A.

8. Takeda America, Takeda U.S.A., and Takeda Limited (collectively, the "Takeda Defendants") have conducted business and derived substantial revenue from Florida, including marketing, disseminating and selling their Actos product in Florida, to patients like the decedent and his prescribing physician, Dr. Terry Seltzer.

9. Takeda America, Takeda U.S.A., and Takeda Limited have derived substantial revenue from goods and products disseminated and used in the State of Florida, including the Actos prescription drug product.

10. Takeda America, Takeda U.S.A., and Takeda Limited purposefully placed the Actos prescription drug product into the stream of commerce, and should have reasonably expected their acts to have consequences within the State of Florida.

11. Takeda America, Takeda U.S.A., and Takeda Limited continuously conducted business in the State of Florida at all times relevant herein.

12. The Takeda Defendants promoted, designed, manufactured, and sold the Actos™ prescription drug product in the State of Florida. Plaintiff was prescribed the Actos™ prescription drug by Dr. Terry Seltzer in the State of Florida. used the Actos drug in Florida, was treated for his bladder cancer in Florida and passed away in the State of Florida.

13. The Takeda defendants purposefully availed themselves of the benefits of conducting business in the State of Florida by designing the Actos product and marketing, promoting, and selling the Actos™ prescription drug to physicians such as Dr. Terry Seltzer and individuals like the decedent.

14. Takeda America, Takeda U.S.A., and Takeda Limited expected or should have expected their acts to have consequences within the State of Florida and derived substantial revenue from interstate commerce.

15. Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

16. Eli Lilly Industries Inc. ("Lilly Industries") is a Delaware corporation with its principal place of business located at 65 De Inf Km 12 6 Ave., Carolina, PR 00979.

17. Lilly and Lilly Industries (collectively the "Eli Lilly Defendants") have transacted and conducted business within the State of Florida, including marketing, promoting, and selling their Actos product in Florida, and to patients like the Plaintiff and his prescribing physician.

18. Lilly and Lilly Industries has derived substantial revenue from goods and products disseminated and used in the State of Florida.

19. Lilly and Lilly Industries purposefully placed the Actos prescription drug product into the stream of commerce and should have reasonably expected their acts to have consequences within the State of Florida.

20. The Lilly Defendants promoted, designed, manufactured, and sold the Actos™ prescription drug product in the State of Florida, including to Plaintiff and his prescribing physician, Dr. Terry Seltzer.

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

JURISDICTION AND VENUE

22. This Court has personal jurisdiction over the Defendants based on Diversity of Citizenship pursuant to 28 U.S.C. Section 1332(a)(1), and the amount in controversy is well in excess of the jurisdictional limit of $75,000.

23. Venue is proper pursuant to 28 U.S.C. 51391 because the claims made in this case, specifically, Mr. GUTIERREZ-OROZCO'S prescription and use of the Actos product, his bladder cancer diagnosis, and his death, occurred in this District.

FACTUAL BACKGROUND

24. The Takeda Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos™, for the treatment of Type II diabetes mellitus.

25. The Eli Lilly Defendants, directly or through their agents, apparent agents, servants or employees designed, marketed, advertised, promoted and sold Actos™, for the treatment of Type II diabetes mellitus.

26. While Actos was designed and manufactured by Takeda, it was marketed and promoted by Eli Lilly in the United States and Europe.

27. According to the American Diabetes Association, Type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

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

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

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

31. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos.

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

33. Actos™ exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos™ is only used to treat Type II diabetes and should not be used to treat Type I diabetes.

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

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

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

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

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

39. As a result of the Takeda and Eli Lilly Defendants' actions and inactions, Plaintiff was injured due to ingestion of Actos™, which caused various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

A. Emergence of the Link Between Actos and Bladder Cancer.

40. Prior to Actos™ being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos™ that produced blood drug levels equivalent to those resulting from a clinical dose.

41. In 2005, the results of the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos™. Dormandy J.A., et al. Secondary Prevention of Macrovascular Events in Patients with Type II Diabetes in the

PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial, Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

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

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

44. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increases of bladder cancer.

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

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

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

48. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos™ and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos™ use, reaching statistical significance after 24 months.

49. Despite FDA finding that Actos™ is linked to a statistically significant increase in the risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and

Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos™.

50. In early 2011, the American Diabetes Association published Piccinni, *et al*. Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

51. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone containing medicines (Actos™, Competact) in France while awaiting the outcome of the ongoing European review.

52. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos™ for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

53. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos™ after Germany's Federal Institute for Drugs and Medical Devices. ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

54. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos™ (pioglitazone) for more than one year may be associated with

an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines.

55. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposure to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos™ for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

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

57. Following the recall in France, Takeda Limited refused to issue a recall of Actos™ in the United States thereby continuing to subject American citizens to the significant risk of developing bladder cancer while ensuring the users in France and Germany were no longer subject to this risk.

58. As the manufacturers and distributors of Actos™, the Takeda and Eli Lilly Defendants knew or should have known that Actos™ use for longer than twelve months was associated with bladder cancer.

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

60. Piccinni, *et al*. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the

reporting odds ratio for pioglitazone was indicative of a "definite risk." Piccinni, *et al*. Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

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

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

63. In 2008, with the knowledge of the risk associated with developing bladder cancer while using Actos™ long term, Takeda Limited achieved its marketing goal by making Actos™ the tenth best-selling medication in the United States all while placing American citizens at risk of developing bladder cancer.

64. On December 12, 2016, the FDA tendered a safety announcement, indicating that "use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer." In particular, it was noted that "[h]ealth care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer." (emphasis in original). Ultimately, the FDA concluded that "[o]verall, the data suggest that pioglitazone use may be linked to an increased risk of bladder cancer."

65. Consumers, including the decedent, who have used Actos™ for treatment of Type II diabetes, have and had several alternative safer products available to treat the conditions and

have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos™ therapy.

66. The Takeda and Eli Lilly Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Actos™ use.

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

PLAINTIFF-SPECIFIC ALLEGATIONS

68. In or around 2008, Plaintiff was prescribed and began taking Actos™ upon the direction of his physician, Dr. Terry Seltzer, for long-term maintenance of his Type II diabetes.

69. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2014. Plaintiff ceased using Actos in or around April 2016. Plaintiff died on April 19, 2017. Plaintiff was unaware of the link between Actos and bladder cancer until approximately April 2016.

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

71. Plaintiff, as a direct and proximate result of long-term Actos™ use, suffered severe mental and physical pain and suffering along with economic loss due to medical expenses.

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

FIRST CAUSE OF ACTION
(STRICT LIABILITY - AS AGAINST THE TAKEDA DEFENDANTS)

73. At all times relevant hereto, the Takeda Defendants manufactured, designed, distributed, marketed, promoted, and/or sold Actos™.

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

75. The Actos™ prescription drug product as distributed by the Takeda Defendants was defective and unreasonably dangerous, as Takeda failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Actos™ therapy as long-term maintenance for Type II diabetes.

76. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

SECOND CAUSE OF ACTION
(STRICT LIABILITY - AS AGAINST THE ELI LILLY DEFENDANTS)

77. At all times relevant hereto, the Eli Lilly Defendants marketed, promoted, and/or sold Actos™ throughout the United States.

78. At all times relevant hereto, the dangerous propensities of Actos™ were known to the Eli Lilly Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they marketed, promoted, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients. Eli Lilly was aware or should have been of the concealed risks of Actos, including bladder cancer, but undertook an aggressive marketing campaign which continued to conceal these risks nonetheless.

79. The Actos™ products as marketed, promoted and by Eli Lilly were defective and unreasonably dangerous prescription drug products, as Eli Lilly failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Actos™ therapy as long-term maintenance for Type II diabetes.

80. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and loss of consortium.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Eli Lilly Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

THIRD CAUSE OF ACTION
(STRICT LIABILITY – DESIGN DEFECT - AS AGAINST THE TAKEDA DEFENDANTS)

81. The Takeda Defendants are strictly liable due to the following acts or omissions relating to their failure to properly design the Actos product:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions

to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

g. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

h. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos™ was manufactured;

j. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

l. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

82. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, bladder cancer and death, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

83. The Takeda Defendants' conduct, as described above, was extreme and outrageous. The Takeda Defendants' risked the lives of the consumers and users of their

products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations.

84. The Takeda Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public of the risks relating to Actos. The Takeda Defendants' outrageous conduct warrants an award of punitive damages.

85. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

FOURTH CAUSE OF ACTION
(FAILURE TO WARN - AS AGAINST THE TAKEDA DEFENDANTS)

86. The Takeda Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Actos. Specifically, the Takeda defendants:

a. failed to investigate, research, study, and define, fully and adequately, the safety profile of Actos;

b. failed to provide adequate warnings about the true safety risks associated with the use of Actos;

c. failed to provide adequate warning regarding the risk and/or increased risk of bladder cancer in patients using Actos;

d. failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos;

e. failed to include a "BOLDED WARNNG" the risk and/or increased risk of bladder cancer in patients using Actos

f. Failed to indicate that current, post-FDA approval signal data shows a much high risk for bladder cancer to occur than indicated in clinical studies;

g. Failed to indicate the true level of increased risk of bladder cancer occurrence when using Actos, even with the warning Takeda did provide;

a. Failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos, even after the 10-year cohort study was completed;

87. By reason of the foregoing, Takeda has become strictly liable in tort to the Plaintiff for the marketing, promoting, distribution, and selling of a defective product, Actos, which the Takeda Defendants placed on the market without adequate warnings. The Takeda Defendants breached their duties by failing to provide a reasonably safe pharmaceutical and adequately warn of same. By virtue of the foregoing, the Takeda defendants are jointly and severally liable for Plaintiff's injuries.

88. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using Actos after FDA approval.

89. Even in December 2016 at the end of the 10-year cohort study which determined that Actos can cause bladder cancer, Takeda failed to update its warning to sufficiently reflect the acute risk of bladder cancer when Actos is used.

90. Indeed, throughout the entire lifetime of the Actos product, from 1999 to the current day, the Takeda Defendants failed to update warnings based on information received from product surveillance after Actos was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

91. Takeda failed to do so because it wished to protect one of its most profitable products.

92. Plaintiff used Actos for its approved purpose and in a manner normally intended and reasonably foreseeable by the Takeda Defendants.

93. Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

94. The Takeda Defendants, as the manufacturers and distributors of Actos, are held to the level of knowledge of an expert in the field.

95. The warnings that were given by the Takeda Defendants were not accurate or clear, and further, were false and ambiguous.

96. The warnings that were given by the Takeda Defendants failed to properly warn physicians of the risks associated with Actos, subjecting Plaintiffs to risks that exceeded the benefits to the Plaintiffs. Plaintiffs, individually and through their physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

97. Takeda Defendants had a continuing duty to warn Plaintiffs and their prescriber of the heightened dangers and inaccurate data associated with its product.

98. Takeda Defendants' inadequate warnings of Actos were acts that amount to willful, wanton, and/or reckless conduct by the Takeda Defendants.

99. These aforementioned warning defects in Takeda Defendants' drug Actos were a proximate cause of Plaintiff's injuries.

100. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, bladder cancer and death, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

101. Defendants' conduct, as described above, was extreme and outrageous. Defendant's risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

102. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

103. **WHEREFORE,** PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

FIFTH CAUSE OF ACTION
(FAILURE TO WARN - AS AGAINST THE ELI LILLY DEFENDANTS)

104. The Eli Lilly Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Actos. Specifically, Eli Lilly:

a. failed to investigate, research, study, and define, fully and adequately, the safety profile of Actos;

b. failed to provide adequate warnings about the true safety risks associated with the use of Actos;

c. failed to provide adequate warning regarding the risk and/or increased risk of bladder cancer in patients using Actos;

d. Failed to indicate that current, post-FDA approval signal data shows a much high risk for bladder cancer to occur than indicated in clinical studies in its marketing and promotional materials ;

e. Failed to indicate the true level of increased risk of bladder cancer occurrence when using Actos, even with the warning Takeda did provide in its marketing and promotional materials ;

f. Failed to include a "BOXED WARNING" about the risk and/or increased risk of bladder cancer in patients using Actos, even after the 10 year cohort study was completed;

105. By reason of the foregoing, Eli Lilly has become strictly liable in tort to the Plaintiff for the marketing, promoting, distribution, and selling of a defective product, Actos, which the Eli Lilly Defendants marketed and promoted in concert with Takeda without adequate warnings. The Eli Lilly Defendants breached their duties by failing to provide a reasonably safe pharmaceutical and adequately warn of same. By virtue of the foregoing, the Eli Lilly defendants are jointly and severally liable for Plaintiff's injuries.

106. A manufacturer exercising reasonable care would have updated its warnings based on reports of injuries to individuals using Actos after FDA approval.

107. Indeed, throughout the entire lifetime of the Actos product, the Eli Lilly Defendants failed to update warnings based on information received from product surveillance after Actos was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

108. Eli Lilly failed to update its marketing or promotional materials as well.

109. Eli Lilly failed to do so because it wished to protect one of its most profitable products.

110. Plaintiff used Actos for its approved purpose and in a manner normally intended and reasonably foreseeable by the Takeda Defendants.

111. Plaintiff and Plaintiffs' healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

112. The Takeda Defendants, as the manufacturers and distributors of Actos, are held to the level of knowledge of an expert in the field.

113. The warnings that were given by the Takeda Defendants were not accurate or clear, and further, were false and ambiguous.

114. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with Actos, subjecting Plaintiffs to risks that exceeded the benefits to the Plaintiffs. Plaintiffs, individually and through their physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

115. Defendants had a continuing duty to warn Plaintiffs and their prescriber of the heightened dangers and inaccurate data associated with its product.

116. Defendants' inadequate warnings of Actos were acts that amount to willful,

wanton, and/or reckless conduct by Defendants.

117. These aforementioned warning defects in Defendants' drug Actos were a proximate cause of Plaintiff's injuries.

118. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

119. The Eli Lilly Defendants' conduct, as described above, was extreme and outrageous. Eli Lilly risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public regarding the true risks of bladder cancer in Actos user populations. Eli Lilly made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Eli Lilly's outrageous conduct warrants an award of punitive damages.

120. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

121. **WHEREFORE,** PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

SIXTH CAUSE OF ACTION
(NEGLIGENCE - AS AGAINST THE TAKEDA DEFENDANTS)

122. At all times relevant hereto, it was the duty of the Takeda Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of the aforesaid Actos™.

123. In disregard of its aforesaid duty, the Takeda Defendants were guilty of one or more of the following negligent acts or omissions:

o. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

p. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

q. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

r. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

s. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

t. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

u. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

v. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its

intended purpose;

w. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos™ was manufactured;

x. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

y. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

z. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

aa. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

bb. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

124. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

SEVENTH CAUSE OF ACTION
(NEGLIGENCE - AS AGAINST THE ELI LILLY DEFENDANTS)

125. At all times relevant hereto, it was the duty of the Eli Lilly Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of the aforesaid Actos™.

126. In disregard of its aforesaid duty, the Eli Lilly Defendants were guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos™ without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos™ while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos™;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos™ was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos™ was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos™;

g. Advertising, marketing, and recommending the use of Actos™, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos™;

h. Representing that Actos™ was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its

intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos™ was manufactured;

j. Continuing to manufacture and sell Actos™ with the knowledge that Actos™ was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos™ so as to avoid the risk of serious harm associated with the use of Actos™;

l. Failing to design and manufacture Actos™ so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos™ and that use of Actos™ created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos™.

127. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

EIGHTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY - AS AGAINST THE TAKEDA DEFENDANTS)

128. The Takeda defendants expressly warranted that Actos was safe and well accepted by users.

129. Actos does not conform to these express representations because Actos is not safe and has numerous serious side effects, many of which were not accurately warned about by the Takeda defendants.

130. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

131. Plaintiff did rely on the express warranties of the Takeda defendants herein.

132. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Actos in recommending, prescribing and dispensing Actos.

133. The Takeda defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

134. Takeda defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Actos was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing and controlling the blood sugar of patients with type II diabetes.

135. Takeda defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Actos was not safe and fit for the use

intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Takeda defendants.

136. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, PLAINTIFF hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

NINTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY - AS AGAINST THE ELI LILLY DEFENDANTS)

137. The Eli Lilly defendants expressly warranted that Actos was safe and well accepted by users, particularly during their marketing and promotional campaign for the Actos drug.

138. Actos does not conform to these express representations because Actos is not safe and has numerous serious side effects, many of which were not accurately warned about by the Takeda defendants.

139. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

140. Plaintiff and his physicians did rely on the express warranties of the Eli Lilly defendants herein.

141. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Eli Lilly defendants for use of Actos in recommending, prescribing and dispensing Actos.

142. The Eli Lilly defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

143. Eli Lilly defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Actos was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing and controlling the blood sugar of patients with type II diabetes.

144. Eli Lilly defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Actos was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Takeda defendants.

145. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Eli Lilly Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

TENTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES - AS AGAINST THE TAKEDA DEFENDANTS)

146. At all times herein mentioned, the Takeda Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and have recently acquired the Takeda Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos to reduce and control blood sugar in type II diabetic patients.

147. At the time Takeda Defendants marketed, sold and distributed Actos for use by Plaintiff, the Takeda Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

148. The Takeda Defendants impliedly represented and warranted to the users of Actos and their physicians, healthcare providers, and the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

149. That said representations and warranties aforementioned were false, misleading and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

150. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

151. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

152. Actos was placed into the stream of commerce by the Takeda Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

153. The Takeda Defendants herein breached the aforesaid implied warranties, as their drug Actos was not fit for its intended purposes and uses.

154. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

ELEVENTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES - AS AGAINST THE ELI LILY DEFENDANTS)

155. At all times herein mentioned, the Eli Lilly Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and have recently acquired the Eli Lilly Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos to reduce and control blood sugar in type II diabetic patients.

156. At the time Eli Lilly Defendants marketed, sold and distributed Actos for use by Plaintiff, Eli Lilly Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

157. The Eli Lilly Defendants impliedly represented and warranted to the users of Actos and their physicians, healthcare providers, and the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

158. Eli Lilly sent employees and agents to market and promote the Actos product, despite its knowledge of the risk of bladder cancer relating to Actos.

159. That said representations and warranties aforementioned were false, misleading and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

160. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

161. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

162. Actos was placed into the stream of commerce by the Eli Lilly Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were

expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

163. The Eli Lilly Defendants herein breached the aforesaid implied warranties, as their drug Actos was not fit for its intended purposes and uses.

164. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Eli Lilly Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

TWELFTH CAUSE OF ACTION
(NEGLIGENCE *PER SE* - AS AGAINST THE TAKEDA DEFENDANTS)

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

166. The package inserts (and other labeling, if any) for each of the Actos products failed to conform to the requirements of 21 U.S.C. §352, including subsections (a), (c), and (f),

or the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), as the package inserts and/or other labeling failed to contain, *inter alia*, information, including warnings and instructions for use, adequate to enable the use of Actos in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use, or to bear "information for its use, including... any relevant hazards, contraindications, side effects, and precautions" that were adequate to enable doctors to "use the drug safely and for the purposes for which it is intended"; and, in addition, contained false, inaccurate, and/or misleading statements concerning their respective products' side effects.

167. With respect to the prescription drug Actos, the Takeda defendants, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b) The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for ACTOS and such deviations are not plainly stated on their labels.

c) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f) The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g) The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

h) The Takeda defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i) The prescription drug Actos is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j) The Takeda defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos' cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k) The Takeda defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

l) The Takeda defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

m) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

n) The Takeda defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

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

p) The prescription drug Actos is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate an upper limit beyond which safety and effectiveness have not been established.

q) The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety, have the identity and strength, and meets the quality and purity characteristic that they purport or are represented to possess.

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

s) The prescription drug Actos violates 21 CFR §211.165 because the test methods employed by the Takeda defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

t) The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

u) The prescription drug Actos violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

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

w) The Takeda defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

x) The Takeda defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

y) The Takeda defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

z) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

aa) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

bb) The Takeda defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up.”

cc) The Takeda defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

dd) The Takeda defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ee) The Takeda defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

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

169. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

THIRTEENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM – AS AGAINST THE TAKEDA DEFENDANTS)

170. At the time of the use of Actos and injuries complained of in the Plaintiffs' Complaint, the Plaintiff ROBIN H REHDERS and Plaintiff JAY ROSENBLUM were married.

171. At the time of decedent's death, Plaintiff ROBIN H REHDERS and Plaintiff JAY ROSENBLUM were also married.

172. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Takeda Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

FOURTEENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM – AS AGAINST THE ELI LILLY DEFENDANTS)

173. At the time of the use of Actos and injuries complained of in the Plaintiffs' Complaint, the Plaintiff ROBIN H REHDERS and Plaintiff JAY ROSENBLUM were married.

174. At the time of decedent's death, Plaintiff ROBIN H REHDERS and Plaintiff JAY ROSENBLUM were also married.

175. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff JAY ROSENBLUM developed and was diagnosed with bladder cancer. Plaintiff have suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, loss of consortium, and death.

WHEREFORE, Plaintiffs hereby demands a trial by jury and judgment against the Eli Lilly Defendants, as follows:

a. For a money judgment representing all pain and suffering and wrongful death damages;

b. For a money judgment representing all lost wages and all economic loss;

c. For a money judgment representing prejudgment interest;

d. For such other and further relief as may be just and proper.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have and or will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury of all issues so triable as a matter of right.

Dated: Coconut Grove, Florida Respectfully submitted,

June 13, 2019

NAPOLI SHKOLNIK, LLC

/s/ Aaron Modiano
2665 S. Bay Shore Drive
Suit 220
Coconut Grove, Florida 33133
(212) 397-1000
Amodiano@Napolilaw.com

and

Nicholas Farnolo (*pro hac vice anticipated*)
400 Broadhollow Rd, Ste 305
Melville, NY 11747
(212) 397-1000
Nfarnolo@napolilaw.com

Attorney(s) for Plaintiff

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

JAY ROSENBLUM and ROBIN H. REHDERS

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nicholas Farnolo; Napoli Shkolnik, PLLC
400 Broadhollow Rd, #305, Melville, NY 11747
(212) 397-1000

DEFENDANTS

Takeda Pharmaceuticals America, Inc., Et Al

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

TORTS

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

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

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

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

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

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

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

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

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

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal injuries due to defective product

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 06/13/2019

SIGNATURE OF ATTORNEY OF RECORD /s/ Nicholas Farnolo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.