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SUPERIOR COURT FOR THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO

RONALD CAPPELLO, MARY CHALK, CAROL COGSWELL, JON MCSPADDEN, SR., FLOYD SHAMBAUGH, PAUL STENBORG, MAUREEN BEAL, RANDAL LITTLE, ARVIS SMITH, DEANNA HEDEGAARD, GRACE GORMAN, POMPILIO RUSO, JEFFREY GOLD, ROBERT MOHARTER, JOE WOOD, THOMAS BLUMM, PAUL HARRIS, JERRY IZENBURG, ROBERT FILIPOVICH SR, KEITH HARRIS, CYNTHIA HESSELING, GLENN HOBBS, ROBERT LOWE, DIANA MOORE, JENNIFER ROBINSON, TERRY SERGEANT, FLOYD SHAMBAUGH, BASIL STEPHANOFF, RANDY CLAPP, DENNIS JOYNER, MICHAEL PRITCHARD, FRANK VOLLMER, JIMMIE BARKER, MICHAEL HOOPER, GARY LATIES, JOHN MOORE, ROGER VALENTINE, JENNER ROSE, JAMES BARTELLE SR, JIMMY FESPERMAN BRADLEY FRANZ, JOHN KENNINGTON, DYHNNE QUINN, GARY TACKLING, EVERETTE EVANS, HUBERT CARROLL, STEVEN JONES, DAVID BARCUS, DONALD BRAY, JESSE CRANFORD JR, JERRY LYLES, GREGORY PANEK, ROBERT TODOR, JEFFREY YELEY, JON-DAVID HALL, MARK JACOB, OTTO KEESLINK JR,

CASE NO.: 37-2019-00026907-CU-PL-CTL

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL:

1. Negligence
2. Negligent – Design Defect
3. Strict Product Liability- Failure to Warn
4. Strict Products Liability – Manufacturing Defect
5. Strict Products Liability – Defective Design
6. Breach of Implied Warranty
7. Breach of Express Warranty

RONALD LONG, ROSE CRAIG, CLARENCE PARAH, SHEILA ESTES, DALLAS DWORSHAK, JAMES FORSYTHE, PHILLIP LOVE, RICHARD SIEVERT, LLOYD STELLFLUE, KENNETH ASBURY SR, RONALD BUDETTE JR, JAMES ELLSMORE, KIMBERLY DOWNY, JOSEPH HARDIN, ERNEST NEWMAN, JOSEPH RITTENBERRY, DANIEL SMITH, RAYMOND NEUDAUER,

Plaintiffs,

vs.

TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED; TAKEDA CALIFORNIA, INC. f/k/a TAKEDA SAN DIEGO, INC., TAKEDA RESEARCH, AND ELI LILLY AND COMPANY,

Defendants.

COMPLAINT FOR DAMAGES

COMES NOW, Plaintiffs RONALD CAPPELLO, MARY CHALK, CAROL COGSWELL, JON MCSPADDEN, SR., FLOYD SHAMBAUGH, PAUL STENBORG, MAUREEN BEAL, RANDAL LITTLE, ARVIS SMITH, DEANNA HEDEGAARD, GRACE GORMAN, POMPILIO RUSO, JEFFREY GOLD, ROBERT MOHARTER, JOE WOOD, THOMAS BLUMM, PAUL HARRIS, JERRY IZENBURG, ROBERT FILIPOVICH SR, KEITH HARRIS, CYNTHIA HESSELING, GLENN HOBBS, ROBERT LOWE, DIANA MOORE, JENNIFER ROBINSON, TERRY SERGEANT, FLOYD SHAMBAUGH, BASIL STEPHANOFF, RANDY CLAPP, DENNIS JOYNER, MAUREEN BEAL, MICHALE PRITCHARD, FRANK VOLLMER, JIMMIE BARKER, MICHAEL HOOPER, GARY LATIES, JOHN MOORE, ROGER VALENTINE, JENNER ROSE,

JAMES BARTELLE SR, JIMMY FESPERMAN. BRADLEY FRANZ, JOHN KENNINGTON, DYHNNE QUINN, GARY TACKLING, EVERETTE EVANS, HUBERT CARROLL, STEVEN JONES, DAVID BARCUS, DONALD BRAY, JESSE CRANFORD JR, JERRY LYLES, GREGORY PANEK, ROBERT TODOR, JEFFREY YELEY, JON-DAVID HALL, MARK JACOB, OTTO KEESLINK JR, RONALD LONG, ROSE CRAIG, CLARENCE PARAH, SHEILA ESTES, DALLAS DWORSHAK, JAMES FORSYTHE, PHILLIP LOVE, RICHARD SIEVERT, LLOYD STELLFLUE, KENNETH ASBURY SR, RONALD BUDETTE JR, JAMES ELLSMORE, KIMBERLY DOWNY, JOSEPH HARDIN, ERNEST NEWMAN, JOSPEH RITTENBERRY, DANIEL SMITH, RAYMOND NEUDAUER, alleges against the defendants TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA PHARMACEUTICALS U.S.A., INC. f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA SAN DIEGO, INC., TAKEDA RESEARCH ELI LILLY AND COMPANY and ELI LILLY INDUSTRIES, INC. (collectively "Defendants") and each of them, as follows:

PARTIES

Plaintiffs RONALD CAPPELLO, MARY CHALK, CAROL COGSWELL, JON MCSPADDEN, SR., FLOYD SHAMBAUGH, PAUL STENBORG, MAUREEN BEAL, RANDAL LITTLE, ARVIS SMITH, DEANNA HEDEGAARD, GRACE GORMAN, POMPILIO RUSO, JEFFREY GOLD, ROBERT MOHARTER, JOE WOOD, THOMAS BLUMM, PAUL HARRIS, JERRY IZENBURG, ROBERT FILIPOVICH SR, KEITH HARRIS, CYNTHIA HESSELING, GLENN HOBBS, ROBERT LOWE, DIANA MOORE, JENNIFER ROBINSON, TERRY SERGEANT, FLOYD SHAMBAUGH, BASIL STEPHANOFF, RANDY CLAPP, DENNIS JOYNER, MAUREEN BEAL, MICHALE PRITCHARD, FRANK VOLLMER, JIMMIE BARKER, MICHAEL HOOPER, GARY LATIES, JOHN MOORE, ROGER VALENTINE, JENNER ROSE,

JAMES BARTELLE SR, JIMMY FESPERMAN. BRADLEY FRANZ, JOHN KENNINGTON, DYHNNE QUINN, GARY TACKLING, EVERETTE EVANS, HUBERT CARROLL, STEVEN JONES, DAVID BARCUS, DONALD BRAY, JESSE CRANFORD JR, JERRY LYLES, GREGORY PANEK, ROBERT TODOR, JEFFREY YELEY, JON-DAVID HALL, MARK JACOB, OTTO KEESLINK JR, RONALD LONG, ROSE CRAIG, CLARENCE PARAH, SHEILA ESTES, DALLAS DWORSHAK, JAMES FORSYTHE, PHILLIP LOVE, RICHARD SIEVERT, LLOYD STELLFLUE, KENNETH ASBURY SR, RONALD BUDETTE JR, JAMES ELLSMORE, KIMBERLY DOWNY, JOSEPH HARDIN, ERNEST NEWMAN, JOSPEH RITTENBERRY, DANIEL SMITH, RAYMOND NEUDAUER, by and through their attorneys NAPOLI SHKOLNIK, LLC, bring this action for personal injuries suffered as a proximate result of Plaintiffs 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.

1. At all times relevant hereto, Plaintiff RONALD CAPPELLO was a resident of the State of California.

2. At all times relevant hereto, Plaintiff MARY CHALK was a resident of the State of Arkansas.

3. At all times relevant hereto, Plaintiff CAROL COGSWELL was a resident of the State of Kentucky.

4. At all times relevant hereto, Plaintiff JON MCSPADDEN was a resident of the State of Georgia.

5. At all times relevant hereto, Plaintiff FLOYD SHAMBAUGH was a resident of the State of Ohio.

6. At all times relevant hereto, Plaintiff RAYMOND NEUDAUER was a resident of the State of Minnesota.

7. At all times relevant hereto, Plaintiff MAUREEN BEAL was a resident of the State of Oregon.

8. At all times relevant hereto, Plaintiff RANDAL LITTLE was a resident of the State of North Carolina.

9. At all times relevant hereto, Plaintiff ARVIS SMITH was a resident of the State of North Carolina.

10. At all times relevant hereto, Plaintiff DEANNA HEDEGAARD was a resident of the State of North Dakota.

11. At all times relevant hereto, Plaintiff GRACE GORMAN was a resident of the State of New Jersey.

12. At all times relevant hereto, Plaintiff POMPILIO RUSSO was a resident of the State of New Jersey.

13. At all times relevant hereto, Plaintiff JEFFREY GOLD was a resident of the State of New Mexico.

14. At all times relevant hereto, Plaintiff ROBERT MOHARTER was a resident of the State of New Mexico.

15. At all times relevant hereto, Plaintiff JOE WOOD was a resident of the State of New Mexico.

16. At all times relevant hereto, Plaintiff THOMAS BLOOM was a resident of the State of Hawaii.

17. At all times relevant hereto, Plaintiff PAUL HARRIS was a resident of the State of Nevada.

18. At all times relevant hereto, Plaintiff JERRY IZENBERG was a resident of the State of Nevada.

19. At all times relevant hereto, Plaintiff ROBERT FILIPOVICH was a resident of the State of Ohio.

20. At all times relevant hereto, Plaintiff KEITH HARRIS was a resident of the State of Ohio.

21. At all times relevant hereto, Plaintiff CYTNHIA HESSELING was a resident of the State of Ohio.

22. At all times relevant hereto, Plaintiff GLENN HOBBS was a resident of the State of Ohio.

23. At all times relevant hereto, Plaintiff ROBERT LOWE was a resident of the State of Ohio.

24. At all times relevant hereto, Plaintiff DIANA MOORE was a resident of the State of Ohio.

25. At all times relevant hereto, Plaintiff JENNIFER ROBINSON was a resident of the State of Ohio.

26. At all times relevant hereto, Plaintiff TERRY SARGENT was a resident of the State of Ohio.

27. At all times relevant hereto, Plaintiff FLOYD SHAMBAUGH was a resident of the State of Ohio.

28. At all times relevant hereto, Plaintiff BASIL STEPHANOFF was a resident of the State of Ohio.

29. At all times relevant hereto, Plaintiff RANDY CLAPP was a resident of the State of Oklahoma.

30. At all times relevant hereto, Plaintiff DENNIS JOYNER was a resident of the State of Oklahoma.

31. At all times relevant hereto, Plaintiff MAUREEN BEAL was a resident of the State of Oregon.

32. At all times relevant hereto, Plaintiff MICHAEL PRITCHARD was a resident of the State of Oregon.

33. At all times relevant hereto, Plaintiff FRANK VOLMER was a resident of the State of Oregon.

34. At all times relevant hereto, Plaintiff JIMMIE BAKER was a resident of the State of Pennsylvania.

35. At all times relevant hereto, Plaintiff MICHAEL HOOPER was a resident of the State of Pennsylvania.

36. At all times relevant hereto, Plaintiff GARY LATIES was a resident of the State of Pennsylvania.

37. At all times relevant hereto, Plaintiff JOHN MOORE was a resident of the State of Pennsylvania.

38. At all times relevant hereto, Plaintiff ROGER VALENTIN was a resident of the State of Pennsylvania.

39. At all times relevant hereto, Plaintiff ROSE JENNER was a resident of the State of Rhode Island.

40. At all times relevant hereto, Plaintiff JAMES BARTELLE was a resident of the State of South Carolina.

41. At all times relevant hereto, Plaintiff JIMMY FERSPERMAN was a resident of the State of South Carolina.

42. At all times relevant hereto, Plaintiff BRADLEY FRANZ was a resident of the State of South Carolina.

43. At all times relevant hereto, Plaintiff JOHN KENNINGTON was a resident of the State of South Carolina.

44. At all times relevant hereto, Plaintiff DHYNNE QUINN was a resident of the State of South Carolina.

45. At all times relevant hereto, Plaintiff GRAY TACKLING was a resident of the State of South Carolina.

46. At all times relevant hereto, Plaintiff EVERETT EVANS was a resident of the State of South Dakota.

47. At all times relevant hereto, Plaintiff HUBERT CARROLL was a resident of the State of Tennessee.

48. At all times relevant hereto, Plaintiff STEVEN JONES was a resident of the State of Tennessee.

49. At all times relevant hereto, Plaintiff DAVID BARCUS was a resident of the State of Texas.

50. At all times relevant hereto, Plaintiff DONALD BRAY was a resident of the State of Texas.

51. At all times relevant hereto, Plaintiff JESSE CRANFORD was a resident of the State of Texas.

52. At all times relevant hereto, Plaintiff JERRY LYLES was a resident of the State of Texas.

53. At all times relevant hereto, Plaintiff GREGORY PANEK was a resident of the State of Texas.

54. At all times relevant hereto, Plaintiff ROBERT TODOR was a resident of the State of Texas.

55. At all times relevant hereto, Plaintiff JEFFREY YELEY was a resident of the State of Texas.

56. At all times relevant hereto, Plaintiff JON-DAVID HALL was a resident of the State of Virginia.

57. At all times relevant hereto, Plaintiff MARK JACOB was a resident of the State of Virginia.

58. At all times relevant hereto, Plaintiff OTTO KEESLING was a resident of the State of Virginia.

59. At all times relevant hereto, Plaintiff RONALD LONG was a resident of the State of Virginia.

60. At all times relevant hereto, Plaintiff ROSE CRAIG was a resident of the State of South Virginia.

61. At all times relevant hereto, Plaintiff CLARENCE STEPHENS was a resident of the State of Virginia.

62. At all times relevant hereto, Plaintiff CLARENCE PARAH was a resident of the State of Vermont.

63. At all times relevant hereto, Plaintiff SHEILA ESTES was a resident of the State of Washington.

64. At all times relevant hereto, Plaintiff DALLAS DWORSHAK was a resident of the State of Wisconsin.

65. At all times relevant hereto, Plaintiff JAMES FORSYTHE was a resident of the State of Wisconsin.

66. At all times relevant hereto, Plaintiff PHILLIP LOVE was a resident of the State of Wisconsin.

67. At all times relevant hereto, Plaintiff RICHARD SIEVERT was a resident of the State of Wisconsin.

68. At all times relevant hereto, Plaintiff LLOYD STELLFUE was a resident of the State of Wisconsin.

69. At all times relevant hereto, Plaintiff KENNETH ASBURY was a resident of the State of West Virginia.

70. At all times relevant hereto, Plaintiff RONALD BURDETTE was a resident of the State of West Virginia.

71. At all times relevant hereto, Plaintiff JAMES ELLSMORE was a resident of the State of New York.

72. At all times relevant hereto, Plaintiff KIMBERLY DOWNEY was a resident of the State of West Virginia.

73. At all times relevant hereto, Plaintiff JOSEPH HARDIN was a resident of the State of West Virginia.

74. At all times relevant hereto, Plaintiff ERNEST NEWMAN was a resident of the State of West Virginia.

75. At all times relevant hereto, Plaintiff JOSEPH RITTENBERRY was a resident of the State of West Virginia.

76. At all times relevant hereto, Plaintiff DANIEL SMITH was a resident of the State of West Virginia.

DEFENDANTS

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

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

79. Takeda America has conducted business and derived substantial revenue from California.

80. Takeda America has derived substantial revenue from goods and products used in the State of California. Takeda America expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

81. 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.

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

83. Takeda U.S.A. has conducted business and derived substantial revenue from California.

84. Takeda U.S.A. has derived substantial revenue from goods and products used in the State of California. Takeda America expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

85. 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.

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

87. Takeda Limited has conducted business and derived substantial revenue from California.

88. Takeda Limited has derived substantial revenue from goods and products used in the State of California. Takeda Limited expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

89. Defendant, Takeda California, Inc., (f/k/a Takeda San Diego, Inc.) is a California corporation, having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121. As part of its business, Takeda California Inc. is and was involved in the research, development, sales and marketing of pharmaceutical products including Actos and Pioglitazone Hydrochloride.

90. Takeda California, Inc. is a wholly-owned subsidiary of Takeda North America.

91. Takeda California, Inc. has transacted and conducted business within the State of California.

92. Takeda California, Inc. has derived substantial revenue from goods and products used in the State of California. Takeda California, Inc. expected or should have expected their acts to have consequences within the State of California, and derived substantial revenue from interstate commerce.

93. Takeda California was heavily involved in the development of Actos/Pioglitazone, the prescription drug product at issue in this litigation.

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

95. Lilly has transacted and conducted business within the State of California.

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

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

JURISDICTION AND VENUE

98. Plaintiffs are informed and believe, and thereon alleges that at all times herein mentioned, each of the Defendants hereto are individuals, corporations, partnerships and/or unincorporated associations organized and existing under and by virtue of the laws of the State of California, or the laws of some other state or foreign jurisdiction, and that said Defendants, and each of them, were and are authorized to do and are doing business in the State of California, and that said Defendants have regularly conducted business in the County of San Diego, State of California.

99. Jurisdiction is proper here because Defendants, including defendant Takeda California, Inc., researched and developed the Actos product within the County of San Diego, State of California.

100. Venue is proper because Defendants, including defendant Takeda California, Inc., researched and developed the Actos product within the County of San Diego, State of California.

101. Defendant Takeda California, Inc. f/k/a Takeda San Diego, Inc., maintains its principal place of business in San Diego at 10410 Science Center Drive, San Diego, CA 92121.

FACTS

101. 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.

102. 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.

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

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

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

106. 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.

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

108. 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.

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

110. 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.

111. 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.

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

113. 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.

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

115. 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.

116. 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").

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

118. 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.

119. 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.

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

121. 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.

122. 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.

123. 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.

124. 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™.

125. 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."

126. 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.

127. 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).

128. 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.

129. 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.

130. 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.

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

132. 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.

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

134. 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.

135. 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.

136. 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.

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

138. 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.

139. 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."

140. Consumers, including Plaintiff, who have used Actos™ for treatment of Type II diabetes, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long-term Actos™ therapy.

141. 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.

142. As a result of Defendants' actions, Plaintiffs and their 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.

NATURE OF THE CASE

143. In or around 2005, Plaintiff ROANLD CAPPELLO was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2012.

144. In or around 2006, Plaintiff MARY CHALKER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around August 2011.

145. In or around 2006, Plaintiff CAROL COGSWELL was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around February 2017.

146. In or around 2008, Plaintiff DENNIS FISHER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around February 2017.

147. In or around 2011, Plaintiff RANDAL LITTLE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around March 2013.

148. In or around 2001, Plaintiff ARVIS SMITH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2016.

149. In or around 2010, Plaintiff JOHN MCSPADDEN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2013.

150. In or around 2007, Plaintiff FLOYD SHAMBAUGH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2017.

151. In or around 2002, Plaintiff DEANNA HEDEGAARD was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around April 2017.

152. In or around 2010, Plaintiff GRACE GORMAN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2016.

153. In or around 2005, Plaintiff POMPILIO RUSSO was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2009.

154. In or around 2007, Plaintiff JEFFREY GOLD was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around November 2016.

155. In or around 2003, Plaintiff ROBERT MOHARTER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2009.

156. In or around 2010, Plaintiff JOE WOOD was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around December 2017.

157. In or around 2011, Plaintiff THOMAS BLUMM was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around March 2017.

158. In or around 1999, Plaintiff PAUL HARRIS was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around Febuary 2004.

159. In or around 2009, Plaintiff JERRY IZENBERG was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2017.

160. In or around 2007, Plaintiff ROBERT FILIPOVICH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2014.

161. In or around 2007, Plaintiff KEITH HARRIS was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around April 2017.

162. In or around 2007, Plaintiff CYNTHIA HESSELING was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around April 2013.

163. In or around 2000, Plaintiff GLENN HOBBS was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2002.

164. In or around 2009, Plaintiff ROBERT LOWE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around December 2016.

165. In or around 2001, Plaintiff DIANA MOORE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around March 2007.

166. In or around 2010, Plaintiff JENNIFER ROBINSON was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around November 2017.

167. In or around 2005, Plaintiff TERRY SARGENT was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2017.

168. In or around 2006, Plaintiff FLOYD SHAMBAUGH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2017.

169. In or around 2004, Plaintiff BASIL STEPHANOFF was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2015.

170. In or around 2010, Plaintiff RANDY CLAPP was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around March 2016.

171. In or around 2010, Plaintiff DENNIS JOYNER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2015.

172. In or around 2001, Plaintiff MAUREEN BEAL was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around March 2017.

173. In or around 2007, Plaintiff MICHAEL PRITCHARD was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2017.

174. In or around 2010, Plaintiff FRANK VOLMER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2017.

175. In or around 2006, Plaintiff JIMMIE BARKER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2016.

176. In or around 2001, Plaintiff MICHAEL HOOPER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around May 2017.

177. In or around 2006, Plaintiff GARY LATIES was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around May 2017.

178. In or around 2002, Plaintiff JOHN MOORE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around February 2015.

179. In or around 2005, Plaintiff ROGER VALENTINE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2014.

180. In or around 2005, Plaintiff JAMES BARTELLE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2017.

181. In or around 2008, Plaintiff JIMMY FESPERMAN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around August 2017.

182. In or around 2010, Plaintiff BRADLEY FRANZ was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around November 2016.

183. In or around 2000, Plaintiff JOHN KENNINGTON was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around December 2016.

184. In or around 2008, Plaintiff DHYNNE QUINN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2010.

185. In or around 2003, Plaintiff GARY TACKLING was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2017.

186. In or around 2007, Plaintiff EVANS EVERETT was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2010.

187. In or around 2007, Plaintiff HUBERT CARROLL was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2015.

188. In or around 2010, Plaintiff STEVEN JONES was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2010.

189. In or around 2010, Plaintiff DAVID BARCUS was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2017.

190. In or around 2009, Plaintiff DONALD BRAY was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2017.

191. In or around 2007, Plaintiff JESSE CRANFORD was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2016.

192. In or around 2003, Plaintiff JERRY LYLES was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around May 2017.

193. In or around 2007, Plaintiff GREGORY PANEK was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around August 2016.

194. In or around 2005, Plaintiff ROBERT TODOR was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2010.

195. In or around 2009, Plaintiff JEFFREY YELEY was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around November 2011.

196. In or around 2008, Plaintiff JON-DAVID HALL was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around December 2017.

197. In or around 2005, Plaintiff MARK JACOB was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around February 2016.

198. In or around 2008, Plaintiff OTTO KEESLING was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2017.

199. In or around 2004, Plaintiff RONALD LONG was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around September 2017.

200. In or around 2008, Plaintiff ROSE CRAIG was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2018.

201. In or around 2005, Plaintiff CLARENCE STEPHENS was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around July 2017.

202. In or around 1999, Plaintiff CALRENCE PARAH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around November 2016.

203. In or around 2001, Plaintiff DALLAS DWORSHAK was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around August 2017.

204. In or around 2002, Plaintiff JAMES FORSYTHE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2009.

205. In or around 2004, Plaintiff PHILLIP LOVE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2012.

206. In or around 2009, Plaintiff RICHARD SIEVERT was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around April 2017.

207. In or around 2007, Plaintiff LLOYD STELLFLUE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around January 2016.

208. In or around 2008, Plaintiff KENNETH ASBURY was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2017.

209. In or around 2006, Plaintiff RONALD BURDETTE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes.

Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around August 2017.

210. In or around 2005, Plaintiff JAMES ELLSMORE was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around July 2016.

211. In or around 2011, Plaintiff KIMBERLY DOWNY was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around July 2017.

212. In or around 2006, Plaintiff JOSEPH HARDIN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around October 2017.

213. In or around 2009, Plaintiff ERNEST NEWMAN was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around June 2016.

214. In or around 2011, Plaintiff JOSPEH RITTENBERRY was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around May 2017.

215. In or around 2002, Plaintiff DANIEL SMITH was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around April 2010.

216. In or around 2010, Plaintiff RAYMOND NEUDAUER was prescribed and began taking Actos™ upon direction of his physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos™, Plaintiff was diagnosed with bladder cancer in or around February 2016.

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

218. Plaintiffs requires and will in the future require ongoing medical care and treatment.

219. Plaintiffs, as a direct and proximate result of long-term Actos™ use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living-related expenses due to his new lifestyle.

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

FIRST CAUSE OF ACTION
[Negligence - Against All Defendants]

221. Plaintiffs hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as to Defendants, and each of them, as follows:

222. Plaintiffs repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

224. In disregard of its aforesaid duty, the 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™.

225. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiffs have developed and been diagnosed with bladder cancer. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiffs prays for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION
[Negligence – Design Defect]

226. Plaintiffs hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to Defendants, and each of them, as follows:

227. At all times relevant hereto, the Defendants manufactured, designed, distributed, and/or sold Actos™.

228. At all times relevant hereto, the dangerous propensities of Actos™ were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and

testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

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

230. As a direct, foreseeable and proximate result of Defendants' defective Actos™ product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products, prescribed for Plaintiff the use of Actos™ for a prolonged and unwarranted period of time. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

WHEREFORE, Plaintiffs prays for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION
[Strict Products Liability – Failure to Warn]

231. Plaintiffs hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to Defendants, and each of them, as follows:

232. Defendants failed to update warnings based on information received from product surveillance after Eliquis was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

233. 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:

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;

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

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

236. Plaintiffs used Actos for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

237. Plaintiffs 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.

238. Defendants, as the manufacturers and distributors of Actos, are held to the level of

knowledge of an expert in the field.

239. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

240. 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.

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

242. Had Plaintiffs or their healthcare providers received adequate warnings regarding the risks associated with the use of Actos, they would not have used it, used an NOAC with an antidote, or they would have used it with blood monitoring.

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

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

245. 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.

246. 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 bleeding in different population. 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.

WHEREFORE, Plaintiffs pray judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION
[Strict Products Liability – Manufacturing Defect – Against All Defendants]

247. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to Defendants, and each of them, as follows:

248. At all times herein mentioned, the Actos product was used in the manner expected and intended by the Plaintiffs.

249. The Actos product was defective at the time of its manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendant, in that, and not by way of limitation, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

250. 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.

251. 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 bleeding in different population. 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.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION
[Strict Products Liability – Design Defect – Against All Defendants]

252. Plaintiffs hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as to Defendants, and each of them, as follows:

253. Plaintiffs repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

255. In disregard of its aforesaid duty, the 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™.

256. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiffs have developed and been diagnosed with bladder cancer. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION
[Breach of Implied Warranty – Against All Defendants]

257. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as to Defendants, and each of them, as follows:

258. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and have recently acquired the 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.

259. At the time Defendants marketed, sold and distributed Actos for use by Plaintiff, 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.

260. The 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.

261. 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.

262. 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.

263. 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.

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

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

266. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION
[Breach of Express Warranty – Against All Defendants]

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

268. Defendants expressly warranted that Actos was safe and well accepted by users.

269. 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 Defendants.

270. 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.

271. Plaintiff did rely on the express warranties of the Defendants herein.

272. 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.

273. The Defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

274. 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.

275. 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 Defendants.

276. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages.

277. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows:

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

2. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;

3. For past and future loss of earnings and earning power, according to proof;

4. For past and future mental and emotional distress, according to proof;

5. For restitution, according to proof;

6. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or is in any other way appropriate.

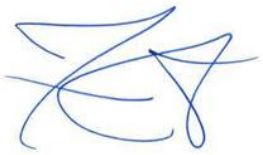
7. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and

8. For such other and further relief as the Court may deem just and proper.

Dated: Los Angeles, California
May 24, 2019

Respectfully submitted,

NAPOLI SHKOLNIK, PLLC



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Attorneys for Plaintiffs

JURY DEMAND

Plaintiff herein demands a trial by jury on all causes of action so triable as of right.

Respectfully submitted this May 24, 2019.

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