IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products Liability Litigation

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7517345

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7465528

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6880711

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7114614

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7225177

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6958012

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7138027

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7267455

MDL No. 6:11-md-2299
JUDGE DOHERTY
MAGISTRATE JUDGE HANNA
Civil Action No.:

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7403141

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7233533

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7541976

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7555092

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7482396

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7262589

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7315564

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7402767

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7439359

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7032689

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7045842

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7125802

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7323914

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6759161

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7280084

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7216372

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6938006

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6891112

Blue Cross and Blue Shield of Massachusetts,

Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7164359

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6893629

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6947432

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7040687

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7539794

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7390323

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 6971012

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7547246

Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., a/s/o Member No. 7164696

Plaintiffs,

vs.

Takeda Pharmaceuticals America Inc., Takeda Pharmaceuticals USA Inc., f/k/a Takeda Pharmaceuticals North America Inc, Takeda Global Research & Development Center Inc., Takeda California Inc., f/k/a Takeda San Diego, Inc., Takeda Pharmaceuticals International Inc., Takeda Pharmaceutical Company Limited; And Eli Lilly and Company

Defendants.

BUNDLED COMPLAINT AND JURY DEMAND

Now come Blue Cross and Blue Shield of Massachusetts, Inc., and its subsidiary, Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., (hereinafter "BCBSMA" or Plaintiffs) as Subrogee of each individual member (1-35) listed herein, by and through its attorneys, Thornton & Naumes, LLP, allege the following upon information and investigation:

JURISDICTION

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

2. Venue of this case is appropriate in the United States District Court for the Western District of Louisiana. Plaintiffs state that, but for the order permitting direct filing into the Western District of Louisiana pursuant to the First General Order, Plaintiffs would have filed in the United States District Court for the District of Massachusetts. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further

proceedings that this case be transferred to the United States District Court for the District of Massachusetts.

NATURE OF THE CASE

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

4. Plaintiffs, BCBSMA, are corporations organized under the laws of the state of Massachusetts and having a principal place of business at the Landmark Center, 401 Park Drive, Boston, Massachusetts. At all relevant times, BCBSMA was authorized to issue policies of health insurance for their members. At the time of injuries alleged herein, BCBSMA had issued a policy of insurance in favor of each insured member identified herein. By virtue of its payment for injuries sustained by an insured member as a direct result of the allegations herein, BCBSMA is subrogated to the rights of their insured members to recover from the person(s) or entity(ies) responsible for said injuries.

PLAINTIFF SPECIFIC ALLEGATIONS

5. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7517345, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2009 to 2013 and as a direct and proximate result, suffered bladder cancer.

6. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7465528, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2006 to 2012 and as a direct and proximate result, suffered bladder cancer.

7. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6880711, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2011 and as a direct and proximate result, suffered bladder cancer.

8. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7114614, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2008 to 2011 and as a direct and proximate result, suffered bladder cancer.

9. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7225177, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2011 to 2012 and as a direct and proximate result, suffered bladder cancer.

10. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6958012, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2010 and as a direct and proximate result, suffered bladder cancer.

11. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7138027, a resident of the state of South Carolina,

who ingested Defendants' pharmaceutical drug Actos from approximately 2005 to 2010 and as a direct and proximate result, suffered bladder cancer.

12. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7267455, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2008 to 2011 and as a direct and proximate result, suffered bladder cancer.

13. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7403141, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2008 to 2012 and as a direct and proximate result, suffered bladder cancer.

14. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7233533, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2010 and as a direct and proximate result, suffered bladder cancer.

15. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7541976, a resident of the state of New York, who ingested Defendants' pharmaceutical drug Actos from approximately 2003 to 2010 and as a direct and proximate result, suffered bladder cancer.

16. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7555092, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2010 and as a direct and proximate result, suffered bladder cancer.

17. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7482396, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2011 and as a direct and proximate result, suffered bladder cancer.

18. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7262589, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2010 to 2012 and as a direct and proximate result, suffered bladder cancer.

19. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7315564, a resident of the state of Florida, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2010 and as a direct and proximate result, suffered bladder cancer.

20. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7402767, a resident of the state of Florida, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2010 and as a direct and proximate result, suffered bladder cancer.

21. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7439359, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2011 and as a direct and proximate result, suffered bladder cancer.

22. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7032689, a resident of the state of Massachusetts,

who ingested Defendants' pharmaceutical drug Actos from approximately 2011 to 2011 and as a direct and proximate result, suffered bladder cancer.

23. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7045842, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2004 to 2011 and as a direct and proximate result, suffered bladder cancer.

24. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7125802, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2011 and as a direct and proximate result, suffered bladder cancer.

25. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7323914, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2010 to 2011 and as a direct and proximate result, suffered bladder cancer.

26. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6759161, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2008 to 2011 and as a direct and proximate result, suffered bladder cancer.

27. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7280084, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2010 and as a direct and proximate result, suffered bladder cancer.

28. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7216372, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2006 to 2010 and as a direct and proximate result, suffered bladder cancer.

29. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6938006, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2010 to 2010 and as a direct and proximate result, suffered bladder cancer.

30. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6891112, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2009 to 2011 and as a direct and proximate result, suffered bladder cancer.

31. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7164359, a resident of the state of Illinois, who ingested Defendants' pharmaceutical drug Actos from approximately 2006 to 2010 and as a direct and proximate result, suffered bladder cancer.

32. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6893629, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2013 and as a direct and proximate result, suffered bladder cancer.

33. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6947432, a resident of the state of Massachusetts,

who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2011 and as a direct and proximate result, suffered bladder cancer.

34. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7040687, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2005 to 2012 and as a direct and proximate result, suffered bladder cancer.

35. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7539794, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2011 and as a direct and proximate result, suffered bladder cancer.

36. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7390323, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2005 to 2011 and as a direct and proximate result, suffered bladder cancer.

37. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 6971012, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2011 and as a direct and proximate result, suffered bladder cancer.

38. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7547246, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2010 to 2010 and as a direct and proximate result, suffered bladder cancer.

39. Plaintiffs, BCBSMA, corporations organized under the laws of the state of Massachusetts, bring this action a/s/o Member 7164696, a resident of the state of Massachusetts, who ingested Defendants' pharmaceutical drug Actos from approximately 2007 to 2011 and as a direct and proximate result, suffered bladder cancer.

PARTY DEFENDANTS

40. Takeda America is a Delaware Corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

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

42. Takeda America has transacted and conducted business within the State of Massachusetts.

43. Takeda America has derived substantial revenue from goods and products used in the State of Massachusetts.

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

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

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

47. Takeda North America has transacted and conducted business within the State of Massachusetts.

48. Takeda North America has derived substantial revenue from goods and products used in the State of Massachusetts.

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

50. Takeda Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan.

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

52. Takeda Limited has transacted and conducted business within the State of Massachusetts.

53. Takeda Limited has derived substantial revenue from goods and products used in the State of Massachusetts.

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

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

56. Lilly has transacted and conducted business within the State of Massachusetts.

57. Lilly has derived substantial revenue from goods and products used in the State of Massachusetts.

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

FACTUAL BACKGROUND

59. 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.

60. ACTOS was jointly launched by Takeda North America and Lilly in 1999.

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

62. 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 doesn't 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.

63. ACTOS was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat type II diabetes. ACTOS is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZD's").

64. 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.

65. ACTOS is sold as a single ingredient product under the brand name ACTOS, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

66. As a result of the defective nature of ACTOS, persons who were prescribed and ingested ACTOS for more than twelve (12) months, including Plaintiffs' insured, have suffered and may continue to suffer from bladder cancer.

67. Defendants concealed and continue to conceal their knowledge that ACTOS can cause bladder cancer from Plaintiffs' insured, other consumers, and the medical community. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with the use of ACTOS for more than twelve (12) months.

68. As a result of Defendants' actions and inactions, Plaintiffs' insured was injured due to ingestion of ACTOS, which caused and will continue to cause Plaintiffs' insured various injuries and damages. Plaintiffs accordingly seek damages incurred by them that are associated with these injuries.

69. 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 does.

70. In 2005, the results of the PROactive (**PRO**spective Pioglit**A**zone **C**linical **T**rial **I**n Macro**V**ascular **E**vents) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using ACTOS. Dormandy J.A., et al. *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomized Controlled Trial*, Lancet, 266:1279-1289 (2005).

71. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS versus comparators. This information was not included in the published Dormandy paper.

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

73. On September 17, 2010, the FDA issued a Safety Announcement stating 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.

74. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from ACTOS.

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

76. On June 9, 2011, the European Medicines Agent ("EMA") announced that is had been informed by the French Medicines Agency ("Afssaps") of its decision to suspend the use of pioglitazone-containing medicines (ACTOS, Competact) in France while awaiting the outcome of the ongoing European review.

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

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

79. June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication ACTOS (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

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

81. On July 12, 2011, Takeda Limited issued a recall on ACTOS in France.

82. As the manufacturers of ACTOS, Defendants knew or should have known that ACTOS use for longer than 12 months was associated with bladder cancer. Instead, Defendants promoted ACTOS as a safe and effective treatment for type II diabetes.

83. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System ("AERS") between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk." *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. Diabetes Care, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

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

85. ACTOS was one of Defendants' top selling drugs. Upon information and belief, in 2011, the medication had global sales of over $4.8 billion and accounted for approximately 27% of Takeda's revenue. In 2008, ACTOS was the tenth best-selling medication in the United States.

86. Consumers, including Plaintiffs' insured, 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.

87. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs' insured and Plaintiffs' insured's physicians the true and significant risks associated with long-term ACTOS use.

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

89. Plaintiffs' insured was prescribed and began taking ACTOS at the direction of a physician. Plaintiffs' insured subsequently developed bladder cancer.

90. As a direct result of being prescribed ACTOS, Plaintiffs' insured has been permanently and severely injured, having suffered serious consequences from ACTOS use. Plaintiffs' insured requires and will in the future require ongoing medical care and treatment.

91. As a direct and proximate result of the use of ACTOS, Plaintiffs' insured suffered severe physical pain and suffering and has and will sustain permanent injuries due to the development of bladder cancer. Plaintiffs made payment for the injuries sustained by their insured member as a direct result of the wrongful conduct of the Defendants.

92. Plaintiffs' insured would not have used ACTOS had Defendants properly disclosed the risks associated with its use.

COUNT I – NEGLIGENCE

93. 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.

94. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of ACTOS to ensure the safety of ACTOS and to ensure that the consuming public, including the Plaintiffs' insured and Plaintiffs' insured's physicians and agents, obtained accurate information and instructions for the use of ACTOS.

95. Defendants owed a duty toward foreseeable users of ACTOS drug products to exercise reasonable care to ensure that ACTOS drugs were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks of increased bladder cancer.

96. Defendants failed to exercise reasonable care in testing ACTOS for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of ACTOS; thus, physicians were not able to make informed choices concerning the use of ACTOS drug products.

97. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of ACTOS into the stream of commerce in that Defendants knew of should have know that ACTOS drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

98. The dangerous propensities of ACTOS drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who

would be expected to prescribe ACTOS for the Plaintiffs' insured and other patients, similarly situated.

99. The information Defendants disseminated to physicians concerning ACTOS drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

100. As a proximate result, the Plaintiffs' insured suffered grievous bodily injuries and consequent economic and other losses from ingesting ACTOS.

101. The Defendants were negligent, and breached their duties of reasonable care to the Plaintiffs' insured with respect to ACTOS drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of ACTOS;

(b) Defendants failed to conduct adequate testing;

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product;

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiffs' insured's physicians or the Plaintiffs' insured that the use of ACTOS drug products could result in severe side effects as described above;

(e) Despite the fact that the Defendants knew or should have known that their ACTOS drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks

associated with ACTOS as set forth above; Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of the Plaintiffs' insured's safety and/or welfare;

(f) Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for ACTOS; and

(g) Defendants, in its promotion of ACTOS, were overly aggressive and deceitful, and promoted ACTOS in a fraudulent manner, despite evidence known to Defendants that ACTOS was dangerous.

102. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiffs' insured developed severe side effects as described herein, suffered irreparable bodily injury, and incurred and will continue to incur expenses for medical treatment, the cost of which was and may continue to be paid for by Plaintiffs.

103. The negligence, carelessness, and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiffs' insured's harms and injuries that Plaintiffs' insured suffered and will continue to suffer.

104. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing ACTOS drug products.

105. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it.

WHEREFORE, Plaintiffs demand compensations for all present and future damages incurred plus interest and costs.

COUNT II – BREACH OF EXPRESS WARRANTY

106. 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.

107. Defendants expressly warranted to the Plaintiffs' insured that ACTOS drug products were safe and effective.

108. In response to these promises and express statements, Plaintiffs' insured and Plaintiffs' insured's physicians relied on such affirmations and warranties.

109. ACTOS drug products do not conform to those express representations in light of recently discovered disclosures and information previously withheld by Defendants. Defendants' express warranty through its false statements failed to disclose design, manufacturing and safety defects inherent in ACTOS.

110. Defendants breached its warranties of ACTOS by continuing sales and marketing campaigns highlighting the safety of its ACTOS drug products, while it knew of the design, manufacturing and safety defects and the risk of bladder cancer as described throughout this Complaint.

111. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiffs' insured developed severe side effects as described herein, suffered irreparable bodily injury, and incurred and will continue to incur expenses for medical treatment, the cost of which was and may continue to be paid for by Plaintiffs.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT III – BREACH OF IMPLIED WARRANTIES

112. 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.

113. The defendants knew that most physicians who prescribed ACTOS drug products were not aware of the serious side effects as described herein associated with the use of ACTOS. The Defendants also knew that the risks of said side effects were much greater than most physicians realized. By failing to give adequate warnings about these side effects and the risk of the use that is associated with those side effects, the Defendants breached implied warranties of merchantability and fitness for the ordinary use of ACTOS.

114. At all times mentioned in this Complaint, the Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold ACTOS drug products and prior to the time ACTOS was used by Plaintiffs' insured, the Defendants impliedly warranted to Plaintiffs' insured and to Plaintiffs' insured's physicians that ACTOS were of merchantable quality and safe and fit for the use for which ACTOS were intended.

115. Plaintiffs' insured relied on the skill and judgment of the Defendants in using ACTOS drug products.

116. ACTOS drug products were not safe and were unfit for their intended use, nor were ACTOS of merchantable quality, as warranted by the Defendants, in that ACTOS had very

dangerous propensities when put to intended use and would cause severe injury to the user. ACTOS drug products were not properly prepared nor accompanied by adequate warnings of ACTOS dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, ACTOS drug products proximately caused Plaintiffs' insured to sustain damages and injuries as alleged in this Complaint.

117. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiffs' insured developed severe side effects as described herein, suffered irreparable bodily injury, and incurred and will continue to incur expenses for medical treatment, the cost of which was and may continue to be paid for by Plaintiffs.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT IV – FRAUDULENT MISREPRESENTATION

118. 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.

119. Defendants had actual knowledge of facts, which demonstrated that representations in the package insert, and/or the PDR monograph, and/or literature, and/or other mediums that the Defendants distributed concerning their ACTOS drug products were false and misleading. Defendants had an absolute duty to disclose the true facts regarding the safety of ACTOS to physicians and their patients and the medical community, which they negligently failed to do. Furthermore, Defendants had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those

representations, to accurately make those representations, and to not make misrepresentations concerning ACTOS, all of which Defendants failed to do.

120. Important information regarding the risk of ACTOS was in the exclusive control of Defendants and was exclusively known by Defendants. In the furtherance of Defendants' own interests, Defendants disseminated false information regarding ACTOS to physicians and Plaintiffs' insured and did so knowing that the safety of ACTOS depended on the accuracy of that information. Further, Defendants knew and expected that recipients of that information would rely on the information that the recipients would take action based upon the information, and that individuals would be put in peril by such actions and that those individuals would suffer physical harm as a result.

121. Defendants expressly and/or impliedly represented to Plaintiffs' insured, Plaintiffs' insured's physicians, the medical community, and members of the general public that their ACTOS drugs were safe for use. The representations by Defendants were, in fact, false. The true facts were that ACTOS was not safe for its intended use and was, in fact, dangerous to the health and body of the Plaintiffs' insured.

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

123. The aforementioned misrepresentations or omissions were made to the Plaintiffs' insured, and Plaintiffs' insured's physicians, and the medical community, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiffs' insured would not have

suffered injuries but for the above misrepresentations or omissions of Defendants. Thus, Defendants and Defendants' misrepresentations or omissions were a cause in fact and proximate cause of Plaintiffs' insured's damages.

124. As a direct and proximate result of the wrongful acts of the Defendants, the Plaintiffs' insured developed severe side effects as described herein, suffered irreparable bodily injury, and incurred and will continue to incur expenses for medical treatment, the cost of which was and may continue to be paid for by Plaintiffs.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT V – FRAUDULENT CONCEALMENT

125. 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.

126. At all times during the course of dealing between Defendants and Plaintiffs' insured, and/or Plaintiffs' insured's healthcare providers, and/or the FDA, Defendants misrepresented the safety of ACTOS for its intended use.

127. Defendants knew or were reckless in not knowing that its representations were false.

128. In representations to Plaintiffs' insured, and/or Plaintiffs' insured's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that ACTOS was not safe;

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

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

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

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

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

g. that ACTOS was manufactured negligently;

h. that ACTOS was manufactured defectively;

i. that ACTOS was manufactured improperly;

j. that ACTOS was designed negligently;

k. that ACTOS was designed defectively; and

l. that ACTOS was designed improperly.

129. Defendants were under a duty to disclose to Plaintiffs' insured, Plaintiffs' insured's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of ACTOS, including but not limited to bladder cancer.

130. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used ACTOS, including the Plaintiffs' insured, in particular.

131. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of ACTOS was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiffs' insured, and Plaintiffs' insured's physicians, hospitals and healthcare providers into reliance, continued use of ACTOS, and actions thereon, and to cause them to purchase, prescribe, and/or dispense ACTOS and/or use the product.

132. Defendants knew that Plaintiffs' insured, and Plaintiffs' insured's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding ACTOS, as set forth herein.

133. Plaintiffs' insured, as well as Plaintiffs' insured's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

134. As a result of the foregoing acts and omissions the Plaintiffs' insured was and still is caused to suffer and/or is at greatly increased risk of serious and dangerous side effects including, inter alia, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature.

135. As a result of the foregoing acts and omissions the Plaintiffs' insured requires and/or will require more health care and services and did incur medical and health expenses. Plaintiffs are informed and believe and further allege that Plaintiffs' insured will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT VI – NEGLIGENT MISREPRESENTATION

136. 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.

137. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiffs' insured, the FDA and the public in general that said product, ACTOS, had been tested and found to be a safe and effective form of therapy.

138. The representations made by Defendants were, in fact, false.

139. Defendants failed to exercise ordinary care in the representation of ACTOS, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented ACTOS high risk of unreasonable, dangerous side effects.

140. Defendants breached their duty in representing ACTOS serious side effects to the medical and healthcare community, to the Plaintiffs' insured, the FDA and the public in general.

141. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that ACTOS had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including inter alia, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature.

142. As a result of the foregoing acts and omissions the Plaintiffs' insured requires and/or will require more health care and services and did incur medical and health expenses. Plaintiffs are informed and believe and further allege that Plaintiffs' insured will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT VII –FRAUD AND DECEIT

143. 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.

144. Defendants conducted research and used ACTOS as part of their research.

145. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including, but not limited to, assuring the public, the Plaintiffs' insured, Plaintiffs' insured's doctors, hospitals, healthcare professions, and/or the FDA that ACTOS was safe and effective for use.

146. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiffs' insured.

147. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiffs' insured, as well as his respective healthcare providers and/or the FDA.

148. The information distributed to the public, the FDA, and the Plaintiffs' insured by Defendants, including, but not limited to, reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

149. The information distributed to the public, the FDA, and the Plaintiffs' insured by Defendants intentionally included representations that Defendants' drug ACTOS was safe and effective for use.

150. The information distributed to the public, the FDA, and the Plaintiffs' insured, by Defendants intentionally included representations that Defendants' drug ACTOS carried the same risks, hazards, and/or dangers as other alternative medications.

151. The information distributed to the public, the FDA, and the Plaintiffs' insured, by Defendants intentionally included false representations that ACTOS was as potentially injurious to the health and/or safety of its intended use as other alternative medications.

152. These representations were all false and misleading.

153. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that ACTOS was not safe.

154. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs' insured, regarding the safety of ACTOS, specifically, but not limited to ACTOS not having dangerous and serious health and/or safety concerns.

155. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiffs' insured, regarding the safety of ACTOS.

156. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiffs' insured, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiffs' insured, to falsely ensure the quality and fitness for use of ACTOS and induce the public, and/or the Plaintiffs' insured to purchase, request, dispense, prescribe, recommend, and/or continue to use ACTOS.

157. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs' insured that ACTOS was fit and safe for its intended use.

158. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs' insured that ACTOS was fit and safe for use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other alternative medications.

159. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiffs' insured that ACTOS did not present serious health and/or safety risks.

160. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiffs' insured that ACTOS did not present health and/or safety risks greater than alternative forms of medication.

161. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

162. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiffs' insured, including Plaintiffs' insured's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiffs' insured and/or Plaintiffs' insured's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiffs' insured to purchase, use, rely on, request, dispense, recommend, and/or prescribe ACTOS.

163. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of ACTOS to the public at large, the Plaintiffs' insured in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

164. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of ACTOS by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of ACTOS.

165. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiffs' insured, as well as Plaintiffs' insured's respective healthcare professionals into a sense of security so that Plaintiffs' insured would rely on the representations and purchase, use and rely on ACTOS and/or that Plaintiffs' insured's respective healthcare providers would dispense, prescribe, and/or recommend the same.

166. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiffs' insured, as well as his respective healthcare professionals would rely upon the information being disseminated.

167. Defendants utilized direct to consumer advertising to market, promote, and/or advertise ACTOS.

168. That the Plaintiffs' insured and/or respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendants' drug ACTOS.

169. That at the time the representations were made, the Plaintiffs' insured and/or respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of ACTOS.

170. That the Plaintiffs' insured did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiffs' insured with reasonable diligence have discovered the true facts.

171. That had the Plaintiffs' insured known the true facts with respect to the dangerous and serious health and/or safety concerns of ACTOS, Plaintiffs' insured would not have purchased, used and/or relied on Defendants' drug ACTOS.

172. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiffs' insured.

173. As a result of the foregoing acts and omissions Plaintiffs' insured was caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, as well as the need for lifelong medical treatment.

174. As a result of the foregoing acts and omissions the Plaintiffs' insured requires and/or will require more health care and services and did incur medical and health related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs' insured will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs demand compensation for all present and future damages incurred plus interest and costs.

COUNT VIII - VIOLATION OF M.G.L. c. 93A

175. 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.

176. At all relevant times hereto the Defendants were engaged in trade or commerce.

177. The acts of the Defendants alleged in Counts I through VII constitute unfair or deceptive acts or practices within the meaning of G.L. c. 93A, §§ 2 and 3, 940 C.M.R. 3.05(1), and 940 C.M.R. 3.16(1) and (2).

178. The actions of the Defendants described herein were performed willfully and knowingly.

179. As a result of the unfair or deceptive acts or practices described in Counts I through VII, the Plaintiffs' insured sustained injury including but not limited to the injuries detailed above, incorporated herein.

WHEREFORE, Plaintiffs demand judgment against the Defendants in an amount that is fair and reasonable; plus treble such amount as provided by M.G.L. c. 93A, sec. 9(3); plus interest, costs, and attorneys' fees to Plaintiffs; and award such other relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

A. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for economic losses, including but not limited to all present and future medical payments made or to be made on behalf of Plaintiffs' insured by Plaintiffs, in such an amount as may be proven at trial;

C. Attorneys' fees, costs and treble damages;

D. Pre-and post-judgment interest; and

E. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Respectfully submitted,

/s/ Marilyn T. McGoldrick

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