UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Phyllis Craig, as Personal Representative of the Estate of John Reuben Craig, 3165 Sandwalk Drive, Kokomo, Indiana 46902	:	
Plaintiff,	:	Case Code Number: 17-697
vs.	:	**COMPLAINT**
JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JANSSEN ORTHO LLC and JOHNSON & JOHNSON	:	**JURY TRIAL DEMANDED**
Defendants.	:	

COMPLAINT

COMES NOW Plaintiff, PHYLLIS CRAIG, as Personal Representative of the Estate of John Reuben Craig, and for causes of action against Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC and Johnson & Johnson. (collectively referred to as Defendants) alleges as follows:

I. INTRODUCTION

1. This is an action for personal injury or survival or, alternatively, wrongful death, statutory, compensatory, and punitive damages due to Plaintiff as a result of Defendants' concealment of risks associated with their drug INVOKANA, their defective design of

INVOKANA, and Defendants' over promotion of the drug for non-approved, or "off-label," indications.

II. JURISDICTION AND VENUE

2. This is an action for damages that exceed the jurisdictional limits of this Court.

3. Venue in this action properly lies in this Court because, Defendants R&D and J&J are organized under the laws of New Jersey; Defendants JPI, R&D, and J&J maintain their principle place of business in the State of New Jersey; and each Defendant at all relevant times conducted substantial business and continued to conduct substantial business in the State of New Jersey.

4. This action is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:-58C-1, *et seq.*, (Products Liability Act), New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.*, (Punitive Damages Act), and common law to recover damages and other relief, including the costs of this action and reasonable attorney's fees, for injuries Plaintiff has sustained as a result of Defendants' acts and omissions in violation of the Product Liability Act and common law. In the alternative, Plaintiff pleads the analogous Indiana statutory and/or common law claims, including but not limited to Indiana Code § 34-11-2-4(a)(1) (Negligence), § 34-20-3-1 (Products Liability), § 34-51-3-2 (Punitive Damages), § 34-11-2-7 (Fraud), § 24-5-0.5-1, *et seq*. (Indiana Deceptive Consumer Sales Act), and § 34-23-1-1 (Wrongful Death) or, alternatively, § 34-9-3-1 (Survival Action).

III. PARTIES

5. Plaintiff, at all relevant times, was a resident of the State of Indiana and used INVOKANA for the treatment of type 2 diabetes, and for other purposes marketed by

Defendants. Plaintiff, Phyllis Craig, is the Personal Representative of the Estate of John Reuben Craig. Plaintiff represents the interests of the Estate of John Reuben Craig and the interests of his surviving spouse and/or heirs. Plaintiff brings this action to recover damages for personal injuries sustained by decedent, John Reuben Craig, after taking INVOKANA. In the alternative, Plaintiff brings this action to recover damages for the wrongful death of decedent, John Reuben Craig, after taking INVOKANA.

6. Defendant JANSSEN PHARMACEUTICAL, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as JPI) is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON.

7. JPI is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

8. At all relevant times, JPI was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug INVOKANA for use as an oral prescription medication.

9. JPI is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON.

10. Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as R&D) is a limited liability company organized under the laws of New Jersey, with a principal place of

business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

11. Defendant R&D is also a subsidiary of Defendant JOHNSON & JOHNSON.

12. As part of its business, R&D is involved in the design, development, research, manufacture, testing, marketing, distribution, and sale of pharmaceutical products, including INVOKANA.

13. At all relevant times, R&D was in the business of and did design, develop, research, test, market, distribute and sell the drug INVOKANA for use as an oral prescription medication.

14. Defendant JANSSEN ORTHO (hereinafter referred to as ORTHO) is a limited liability company organized under the laws of Delaware, having its principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778.

15. Defendant Ortho is also a subsidiary of Defendant JOHNSON & JOHNSON.

16. As part of its business, ORTHO is involved in the design, development, research, testing, manufacture, marketing, distribution and sale of pharmaceutical products, including INVOKANA.

17. At all relevant times, ORTHO was in the business of and did design, develop, research, manufacture, test, advertise, promote, market, sell and distribute the drug INVOKANA for use as an oral prescription medication.

18. Defendant JOHNSON & JOHNSON (hereinafter referred to as J&J) is a fictitious name adopted by Defendant Johnson & Johnson Company, a New Jersey corporation with its

principle place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

19. As part of its business, J&J and its "family of companies," including each and every other Defendant named herein, is involved in the design, development, research, marketing, distribution and sale of pharmaceutical products, including INVOKANA.

20. At all times herein mentioned, each Defendant was the agent, servant, partner, predecessor in interest, and joint venture of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

IV. FACTUAL BACKGROUND

21. In March 2013, the United States Food and Drug Administration (FDA) approved Defendants' compound *Canigliflozin*, marketed by defendants as INVOKANA, for the treatment of type 2 diabetes.

22. INVOKANA is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 (SGLT2) inhibitors.

23. Defendant J&J, in collaboration with its Japanese partner, initiated the initial design and development of INVOKANA.

24. Defendant J&J identifies in its 2010 annual report that "Canagliflozin is developed in collaboration with Mitsubishi-Tanabe Pharma Corporation."

25. Defendant J&J paid over $53,000 in fees, reimbursements, and honoria to a consultant for work the consultant performed in regards to INVOKANA's clinical trials.

26. Defendant JPI, acquired the marketing rights to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in the United States, including in the State of New Jersey, and Plaintiff's home state, in collaboration with its parent, subsidiaries, and partners, including each and every Defendant named herein.

27. Defendant R&D, in collaboration with Defendant JPI, conducted clinical research, and testing which Defendants submitted to the FDA in support of INVOKANA's approval.

28. Defendant Ortho is known to manufacture INVOKANA, in collaboration with its partners, including each and every Defendant named herein.

29. In designing, developing, researching, testing, manufacturing, distributing, and selling INVOKANA, each and every Defendant named herein acted in concert, or as each other's agents, in furtherance of their joint enterprise, acting with the common goal to develop, manufacture, and sell INVOKANA to consumers, including Decedent.

30. With 2015 sales of $1.3 billion, INVOKANA is one of Defendants' blockbuster drugs, even though it has only been on the market a few years.

31. INVOKANA's 2015 sales figures represent a 123% increase from the previous year's sales.

32. INVOKANA's tremendous sales figures are due to Defendants substantial marketing efforts directed to consumers and the medical community.

33. Since INVOKANA has been available to U.S. consumers, Defendants have spent nearly $27 million on INVOKANA related payments to doctors and hospitals.

34. INVOKANA is indicated only for treating type 2 diabetes.

35. Though INVOKANA is indicated only for this limited use, Defendants intentionally mislead consumers into believing that INVOKANA is indicated for weight loss, and has cardiovascular benefits.

36. INVOKANA is designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, an estimated 60% of glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease; resulting in increased stress on INVOKANA users' kidneys.

37. Because INVOKANA prevents a person from using a significant amount of the body's primary fuel, glucose, INVOKANA users must turn to an alternate fuel source, fat. As the body begins to breakdown fat for fuel, acids called ketones are introduced into the blood stream, creating the potential for acidosis (increased acidity in the blood).

38. Because Defendants designed INVOKANA to lower blood-glucose in this way, INVOKANA users are at an increased and unreasonable risk of developing ketoacidosis, and severe kidney injuries, including renal failure.

39. Generally, when a person is suffering from ketoacidosis (excess ketones), they also report high blood-glucose levels, and frequent urination.

40. Normally, the body excretes excess ketones through urination in order to obtain proper blood-acid balance; however, because INVOKANA already places the kidneys under duress by forcing significant quantities of unmetabolized glucose through the urinary tract as everyday treatment for managing type 2 diabetes, INVOKANA users often are unable to obtain blood-acid balance through the normal process, urination, and frequently require medical intervention to prevent the acidosis from becoming life threatening.

41. Under normal circumstances, a person relies on the emergency jettison of excess glucose and ketones to maintain blood-acid balance through frequent urination only when in dire need.

42. Thus, INVOKANA's mechanism to treat high blood-glucose, expelling unmetabolized glucose through the urinary tract, which causes more frequent urination, is a process the body usually reserves for elevated glucose or acidosis emergencies.

43. INVOKANA forces this emergency process on its users in the normal course of treatment- every day.

44. Generally, ketoacidosis is rare for type 2 diabetics, but much more common in type 1 diabetics. Type 1 diabetics are at a greater risk of suffering ketoacidosis because, like INVOKANA users, their bodies are unable to metabolize glucose for fuel, leaving a significant quantity to be expelled through the kidneys and out the urinary tract, forcing the body to turn to fat for fuel.

45. Ketoacidosis can lead to organ failure, including renal failure if not treated quickly.

46. Unfortunately for INVOKANA users, because the drug mimics a naturally occurring emergency process while lowering blood-glucose, key symptoms of ketoacidosis such as elevated blood-glucose and frequent urination are either not present or unrecognizable. Thus, INVOKANA users are often unaware they are suffering ketoacidosis until more severe injuries develop.

47. Since INVOKANA's introduction to U.S. consumers, the FDA has received a significant number of reports of diabetic ketoacidosis, and kidney injuries, including renal failure and kidney infection, among users of INVOKANA.

48. On May 15, 2015, the FDA issued a Public Health Advisory linking SGLT2 inhibitors, including INVOKANA, to diabetic ketoacidosis.

49. Recently, on December 4, 2015, it was the FDA that updated INVOKANA's warning label to warn of too much acid in the blood (ketoacidosis), and serious urinary tract infections, which can develop into full blown kidney infections.

50. Then, on June 14, 2016, the FDA required Defendants to strengthen the INVOKANA warning label by including the risk of acute kidney injury.

51. An analysis of the FDA adverse event database shows that patients taking INVOKANA are several times more likely to report diabetic ketoacidosis, and acute kidney injury, including renal failure, than those taking other diabetes drugs to treat high blood-glucose.

52. Defendants' clinical trials and other data available to Defendants before they sold INVOKANA to Decedent indicated that INVOKANA causes renal failure, or increases the risk of the occurrence of renal failure.

53. Given the state of the scientific field, Defendants intentional design of INVOKANA, and the data generated through Defendants' phase I- IV clinical trials, post marketing trials, and reported adverse events, Defendants' knew or should have known before they sold INVOKANA to Decedent that INVOKANA was likely to cause Decedent's harm as complained of herein.

54. Despite Defendants' knowledge of the increased risk of severe injury among INVOKANA users, Defendants did not warn consumers but instead continued to defend INVOKANA, mislead physicians and the public, and minimize unfavorable findings.

55. Defendants' failure to warn about diabetic ketoacidosis is particularly detrimental to those taking the drug because in many cases of INVOKANA induced ketoacidosis, the signs of ketoacidosis are masked by the effects of the drug.

56. Consumers, including Decedent, who have used INVOKANA for treatment of diabetes, have several alternative safer products available to treat the conditions, such as Metformin, Onglyza, Januvia and Jardiance.

57. Defendants knew of the significant risk of severe injury caused by ingestion of INVOKANA. However, Defendants did not adequately and sufficiently warn consumers, including Decedent, or the medical community of the severity of such risks.

58. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of INVOKANA and willfully deceived Decedent, his health care professionals, the medical community, and the general public as to the benefits, health risks and consequences of the use of INVOKANA.

59. As a direct result, on or about September 15, 2014, Defendants sold INVOKANA to Decedent, and Decedent began taking it to treat type 2 diabetes, and for other reasons marketed by Defendants.

60. Decedent ingested and used INVOKANA as prescribed and in a foreseeable manner.

61. The INVOKANA used by Decedent was provided to him in a condition substantially the same as the condition in which it was manufactured and sold by Defendants.

62. Decedent agreed to initiate treatment with INVOKANA in an effort to reduce his blood-glucose, and because he was misled by Defendants into believing INVOKANA possesses indications or benefits which it does not.

63. Instead of being safe and effective as INVOKANA's alternatives are, INVOKANA can cause severe injuries, such as those suffered by Decedent, and INVOKANA has not been approved nor deemed safe and effective for either weight loss or reducing blood pressure, as Defendants represent.

64. After beginning INVOKANA treatment on or about September 15, 2014 and continuing to on or about February 2, 2015, and as a direct and proximate result thereof, Decedent suffered acute kidney injury in February of 2015, requiring hospitalization and continued treatment.

65. In the alternative, after beginning INVOKANA treatment on or about September 15, 2014 and continuing through February 2015, and as a direct and proximate result thereof, Decedent died on October 11, 2015.

66. Prior to ingesting INVOKANA, Decedent exhibited no indication that he was at risk of acute kidney injury, including but not limited to kidney failure, renal failure or complications arising therefrom.

67. Because Defendants concealed the true risks of INVOKANA from Decedent and Decedent's physicians, at the time Decedent was injured, Decedent and Plaintiff had no way of knowing that INVOKANA was the cause, and that Defendants' conduct in the design,

development, researching, testing, manufacturing, advertising, distribution and sale subjects them to liability for Decedent's injuries.

68. Defendants knew or should have known the risks associated with the use of INVOKANA, including the risk of developing severe and sometimes fatal kidney injuries, including ketoacidosis.

69. The development of Decedent's injuries, or alternatively, subsequent death were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA. This conduct, as well as the product defects complained of herein, were substantial factors in bringing about and exacerbating Decedent's injuries or, in the alternative, Decedent's death.

70. Decedent's injuries or, alternatively, death were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's defects.

71. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly designed, developed, researched, tested, marketed, distributed and sold INVOKANA without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

72. Decedent would not have used INVOKANA had Defendants properly disclosed the risks associated with the drug, or had not overstated INVOKANA's benefits. Thus, had Defendants properly disclosed the risks and benefits associated with INVOKANA, Decedent

would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA.

73. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and his physicians the true and significant risks associated with taking INVOKANA.

74. As a result of Defendants' actions, Decedent and his prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Decedent had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

75. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Decedent suffered severe and permanent physical and emotional injuries. Until his death, Decedent endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

76. Until his death, Decedent suffered from mental anguish from the knowledge that he may have suffered life-long complications as a result of the injuries caused by INVOKANA.

V. DELAYED DISCOVERY

77. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and Decedent's physicians and healthcare providers the true and significant risks associated with INVOKANA.

78. As a result of Defendants' actions, Decedent and Decedent's physicians and healthcare providers were unaware, and could not have reasonably known or have learned

through reasonable diligence, that Decedent had been exposed to the risks identified in this Complaint, and that those risks were the results of Defendants' acts, omissions, and misrepresentations.

79. The accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

VI. COUNTS

COUNT I
STRICT LIABILITY- DEFECTIVE DESIGN
(N.J. Products Liability Act – N.J.S.A. 2A:58C-1, *et seq.*)

79. Plaintiff restates the allegations set forth above as if fully rewritten herein.

80. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing INVOKANA. Through that conduct, Defendants knowingly and intentionally placed INVOKANA into the stream of commerce with full knowledge that it reaches consumers, such as Decedent, who ingested it.

81. The design, development, testing, and research of INVOKANA occurred at Defendants JPI, R&D, and J&J's principle place of business, respectively, in the State of New Jersey, and various other facilities which Defendants maintain in the State of New Jersey.

82. INVOKANA was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Decedent.

80. Defendants placed INVOKANA into the stream of commerce with wanton and reckless disregard for the public safety.

81. INVOKANA was in an unsafe, defective, and inherently dangers condition.

82. INVOKANA contains defects in its design which render the drug dangerous to consumers, such as Decedent, when used as intended or as a reasonably foreseeable to Defendants. The design defects render INVOKANA more dangerous than other diabetes medications and cause an unreasonable increased risk of injury, including but not limited to renal failure, renal impairment, renal insufficiency and ketoacidosis.

83. INVOKANA was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that INVOKANA was defective and unsafe, even when used as instructed.

84. The nature and magnitude of the risk of harm associated with the design of INVOKANA, including the risk of renal failure, renal impairment, renal insufficiency and ketoacidosis, is high in light of the intended and reasonably foreseeable use of INVOKANA.

85. The risks of harm associated with the design of INVOKANA are higher than necessary.

86. It is highly unlikely that INVOKANA users would be aware of the risks associated with INVOKANA through either warnings, general knowledge or otherwise, and Decedent specifically was not aware of these risks, nor would he expect them.

87. The design did not conform to any applicable public or private product standard that was in effect when the INVOKANA left Defendants' control.

88. INVOKANA's design is more dangerous than a reasonably prudent consumer would expect when in its intended or reasonably foreseeable manner. It was more dangerous than Decedent expected.

89. The intended or actual utility of INVOKANA is not of such benefit or to justify the risk of renal failure, renal impairment, renal insufficiency and ketoacidosis or the complications flowing therefrom.

90. At the time INVOKANA left Defendants' control, it was both technically and economically feasible to have an alternative design that would not cause renal failure, renal impairment, renal insufficiency and ketoacidosis, or an alternative design that would have substantially reduced the risk of these injuries.

91. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Decedent.

92. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Decedent, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

93. The unreasonably dangerous nature of INVOKANA caused serious harm to Decedent

94. Decedent's kidneys were injured, causing renal failure, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

95. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Defendant, thereby entitling Plaintiff

to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

96. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, until his death, Decedent suffered personal and economic injuries. In addition, until his death, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
STRICT LIABILITY- FAILURE TO WARN
(N.J. Products Liability Act- N.J.S.A. 2A:58C-1, *et seq.*)

97. Plaintiff restates the allegations set forth above as if fully rewritten herein.

98. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing INVOKANA. Through that conduct, Defendants knowingly and intentionally placed INVOKANA into the stream of commerce with full knowledge that it reaches consumers, such as Decedent, who ingested it.

99. The design, development, testing, researching, labeling and marketing of INVOKANA occurred at Defendants JPI, R&D, and J&J's principle place of business, respectively, in the State of New Jersey, and various other facilities which Defendants maintain in the State of New Jersey.

100. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released INVOKANA into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted INVOKANA to the FDA, health care professionals, Decedent, and other consumers, and therefore had a duty to warn of the risks associated with the use of INVOKANA.

101. Defendants expected INVOKANA to reach, and it did in fact reach, prescribing health care professionals and consumers, including Decedent and his prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

102. INVOKANA, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious and sometimes fatal bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

103. INVOKANA's prescribing information fails to adequately warn of the injuries complained of herein in that it:

a. provides no warning of injury to the kidney, such as renal failure;

b. downplays the risk of harm by indicating only patients with preexisting renal impairment are at risk of suffering a renal related adverse event;

c. does not warn that INVOKANA can cause permanent injury to the kidneys; and

d. downplays the risk of harm by including relevant information in the "Adverse Events" section rather than the "Warnings and Precautions" section.

104. Instead, prior to the FDA's mandated label change on June 16, 2016, INVOKANA's warning label merely notes that INVOKANA may impair renal function specifically stating "Impairment in Renal Function: Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL/min1.73 m^2 (2.2)."

105. Instead of warning of kidney injuries, Defendants go on to note in the "Adverse Reactions" section, not the "Warnings and Precautions" section, that INVOKANA was associated with renal-related adverse reactions "particularly in patients with moderate renal impairment."

106. Thus, in addition to failing to include any mention of kidney injuries in the warnings section, Defendants also mislead and downplay the risk of kidney injuries by indicating only patients with preexisting renal impairment are at risk of suffering any kidney related adverse events.

107. Moreover, renal function merely relates to the kidneys' ability to filter waste, and warning that the drug may impair renal function is not adequate to warn consumers and the medical community that the drug actually causes permanent harm to the kidneys, especially in light of Defendants attempt to downplay the risk of adverse events.

108. As described above, INVOKANA was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Decedent. INVOKANA contained warnings insufficient to alert consumers, including Decedent, to the dangerous risks and reactions associated with INVOKANA, including the development of Decedent's injuries.

109. At the time Defendants' sold INVOKANA to Decedent, Defendants knew or should have known, based on their intentional design, pre-approval clinical trial data, post approval clinical trial data, and reported adverse events that INVOKANA can cause renal failure and complications therefrom and that their warning was inadequate.

110. This defect caused serious injury to Decedent, who used INVOKANA for its intended purpose and in a reasonably anticipated manner.

111. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure INVOKANA did not cause users to suffer from unreasonable and dangerous risks.

112. Defendants negligently and recklessly labeled, distributed, and promoted INVOKANA because they knew or should have known of INVOKANA's defective nature, but failed to adequately warn consumers and the medical community.

113. Defendants had a continuing duty to warn Decedent of the dangers associated with INVOKANA.

114. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

115. Decedent could not have discovered any defects in INVOKANA through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

116. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that INVOKANA caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of INVOKANA, as referenced above, were known to Defendants, before they sold INVOKANA to Decedent, through Defendants' pre-approval clinical trial data, post approval clinical trial data, and reported adverse events, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

117. INVOKANA, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Decedent, in a reasonable and intended manner without knowledge of this risk of serious bodily harm.

118. Defendants knew or should have known that the limited warnings disseminated with INVOKANA were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

119. Defendants communicated to health care professionals' information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of INVOKANA;

b. continued to aggressively promote INVOKANA even after Defendants knew or should have known of the unreasonable risks from use;

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of INVOKANA's effect on the kidneys;

e. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and

f. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of INVOKANA.

120. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of INVOKANA.

121. Due to these deficiencies and inadequacies, INVOKANA was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

122. Had Defendants properly disclosed and disseminated the risks associated with INVOKANA, Decedent would have avoided the risk of developing injuries as alleged herein by choosing a safer alternative product such as Metformin, Januvia, Onglyza or Jardiance.

123. The safer alternative diabetes prescription medications do not present the risk of injury as complained of herein, and they are otherwise safe and effective for the treatment of type 2 diabetes.

124. Instead, because of Defendants' false and misleading advertising, directed at consumers such as Decedent, and the medical community, such as Decedent's physicians, Decedent began treatment with INVOKANA.

125. Decedent's kidneys were injured, causing renal failure and complications therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

126. Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of INVOKANA and the risks associated with its use.

127. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

128. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
NEGLIGENCE

129. Plaintiff restates the allegations set forth above as if fully rewritten herein.

130. Defendants directly or indirectly caused INVOKANA to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Decedent.

131. The Defendants owed Decedent and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Decedent and other consumers of the dangers associated with INVOKANA.

132. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of INVOKANA.

133. Defendants had a duty to disclose to health care professionals the causal relationship or association of INVOKANA to the development of Decedent's injuries.

134. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of INVOKANA, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of INVOKANA, including the injuries suffered by Decedent.

135. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold INVOKANA, Defendants knew, or in the exercise of reasonable care should have known, that their product was defective, dangerous, and otherwise harmful to Decedent.

136. Defendants knew, or in the exercise of reasonable care should have known, that the use of INVOKANA could cause or be associated with Decedent's injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

137. Defendants knew that many health care professionals were prescribing INVOKANA, and that many patients developed serious side effects including but not limited to severe kidney damage.

138. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of INVOKANA in interstate commerce, in that Defendants knew and had reason to know that a consumer's use and ingestion of INVOKANA created a significant risk of suffering unreasonably dangerous health related side effects, including Decedent's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

139. Defendants were further negligent in that they manufactured and produced a defective product, INVOKANA, knew and were aware of the defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the product's defects and risks.

140. The Defendants' failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test INVOKANA before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of INVOKANA;

c. failing to conduct sufficient post-market testing and surveillance of INVOKANA;

d. designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA to consumers, including Decedent, without an adequate warning of the significant and dangerous risks of INVOKANA and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of INVOKANA's effect on the kidneys;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment;

h. failing to exercise due care when advertising and promoting INVOKANA; and

i. negligently continuing to manufacture, market, advertise, and distribute INVOKANA after the Defendants knew or should have known of its adverse effects.

141. Defendants knew and/or should have known that it was foreseeable that consumers such as Decedent would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of INVOKANA.

142. Decedent did not know the nature and extent of the injuries that could result from ingestion and use of INVOKANA

143. But for Defendants' negligent conduct, Decedent would have avoided harm by choosing a safer alternative treatment.

144. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Decedent suffered as described herein because INVOKANA's intended design causes kidney failure and complications arising therefrom.

145. Decedent's kidneys were injured, causing renal failure and complications arising therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

146. Defendants' conduct, as described above, was reckless. Defendants' actions and inaction risked the lives of consumers and users of their products, including Decedent.

147. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

148. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred

medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IV
BREACH OF EXPRESS WARRANTY

149. Plaintiff restates the allegations set forth above as if fully rewritten herein.

150. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing INVOKANA, which is unreasonably dangerous and defective, thereby placing INVOKANA into the stream of commerce.

151. Defendants made express representations to Decedent before and at the time of sale through various advertising, and prescribing material. For instance, Defendants prominently claim in their advertisements directed at the medical community and consumers, such as Decedent, "Greater Reductions in body weight"; and "Greater Reductions in systolic blood pressure."

152. Additionally, Defendants prominently display a heart on their advertising directed at consumers, including Decedent, representing that INVOKANA provides cardiovascular benefits even though the FDA has approved no such indication.

153. Further, Defendants expressly represented to Decedent, other consumers, Decedent's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that INVOKANA:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. was approved, and deemed safe and effective for weight loss;

d. was approved, and deemed safe and effective for reducing blood pressure;

e. did not produce any dangerous side effects, and

f. had been adequately tested and found to be safe and effective for the treatment of diabetes.

154. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with use of INVOKANA. In fact, Defendants knew or should have known that the risks identified in INVOKANA's prescribing information and package inserts do not accurately or adequately set forth the drug's true risks. Despite this, Defendants expressly warranted INVOKANA as safe and effective for use for approved and unapproved indications.

155. Defendants advertised, labeled, marketed, and promoted INVOKANA, representing the quality to health care professionals, Decedent, and the public in such a way as to induce INVOKANA's purchase or use, thereby making an express warranty that INVOKANA

would conform to the representations. More specifically, the prescribing information for INVOKANA did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

156. Despite this, Defendants expressly represented that INVOKANA was safe and effective, that it was safe and effective for use by individuals such as Decedent, and/or that it was safe and effective to treat diabetes, safe and effective for weight loss, and safe and effective to reduce blood pressure. Portions of the prescribing information relied upon by Decedent and his health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurately nor adequately set forth.

157. The representations about INVOKANA contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

158. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects which Defendants do not warn of, causes severe and permanent injuries, and because INVOKANA is not approved for weight loss or reducing blood pressure, as represented by Defendants. Therefore, Defendants breached the aforementioned warranties.

159. At all relevant times, INVOKANA did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

160. Neither Decedent nor his prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning INVOKANA when Defendants sold INVOKANA to Decedent.

161. Decedent, other consumers, Decedent's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting INVOKANA.

162. Had the prescribing information for INVOKANA accurately and adequately set forth the true risks associated with the use of such product, including Decedent's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Decedent could have avoided the injuries complained of herein by seeking a safer alternative treatment.

163. After purchasing INVOKANA from Defendants and subsequently ingesting it, Decedent's kidneys were injured, causing renal failure and complications arising therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

164. Defendants' conduct as described above was committed with gross negligence an fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

165. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT V
BREACH OF IMPLIED WARRANTY

166. Plaintiff restates the allegations set forth above as if fully rewritten herein.

167. Defendants manufactured, distributed, advertised, promoted, and sold INVOKANA.

168. At all relevant times, Defendants knew of the use for which INVOKANA was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

169. Defendants were aware that consumers, including Decedent, would use INVOKANA for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, and reduced blood pressure.

170. INVOKANA was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA has dangerous propensities when used as intended and can cause serious injuries, including kidney failure.

171. At all relevant times, Defendants intended that INVOKANA be used in the manner used by Decedent, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that INVOKANA was not adequately tested.

172. Defendants were aware that consumers, including Decedent, would use INVOKANA as marketed by Defendants. As such, Decedent was a foreseeable user of INVOKANA.

173. Upon information and belief, Decedent and/or his health care professionals were at all relevant times in privity with Defendants.

174. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Decedent's injuries without adequately warning of said risks.

175. Decedent and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell INVOKANA only if it was indeed of merchantable quality and safe and fit for its intended use.

176. Defendants breached their implied warranty to consumers, including Decedent. INVOKANA was not of merchantable quality, nor was it safe and fit for its intended use.

177. Decedent and his physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

178. Decedent's use of INVOKANA was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

179. INVOKANA was expected to reach and did in fact reach consumers, including Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

180. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous as described above and caused undue injuries, including Decedent's injuries.

181. The harm caused by INVOKANA far outweighed its alleged benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

182. Neither Decedent nor his health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with INVOKANA.

183. Defendants' breach of these implied warranties induced Decedent to purchase INVOKANA from Defendants.

184. After purchasing and ingesting INVOKANA, Decedent's kidneys were injured, causing renal failure and complications arising therefore, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

185. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of

human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

186. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VI
FRAUDULENT MISREPRESENTATION

187. Plaintiff restates the allegations set forth above as if fully rewritten herein.

188. Defendants made fraudulent misrepresentations with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory

submissions that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes;

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications;

c. Defendants represented that INVOKANA had been approved and deemed safe and effective for weight loss; and

d. Defendants represented that INVOKANA had been approved and deemed safe and effective for reducing blood pressure.

189. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of INVOKANA to Decedent, other consumers, Decedent's physicians, and the medical community.

190. In furtherance of their aggressive and misleading marketing campaign, the representations were made by the Defendants with the intent that doctors and patients, including Decedent and his physicians, rely upon them.

191. Defendants' representations were made with the intent of defrauding and deceiving Decedent, other consumers, Decedent's physicians, and the medical community to induce and encourage the sale of INVOKANA.

192. Decedent, his doctors, and others reasonably relied upon these representations.

193. But for Defendants' misrepresentations, Decedent would have not purchased INVOKANA.

194. After purchasing and subsequently ingesting INVOKANA, Decedent's kidneys were injured, causing renal failure and complications arising therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

195. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

196. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VII
NEGLIGENT MISREPRESENTATION

197. Plaintiff restates the allegations set forth above as if fully rewritten herein.

198. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning INVOKANA, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

199. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of INVOKANA with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest INVOKANA.

200. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals and consumers of INVOKANA rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting INVOKANA.

201. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of INVOKANA were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Decedent.

202. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals would write prescriptions for INVOKANA in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for INVOKANA would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

203. From the time INVOKANA was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts, or misrepresented material facts, regarding the safety, indications, and efficacy of INVOKANA. Defendants made material misrepresentations to Decedent, his health care professionals, the healthcare community, and the general public, including:

a. stating that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies;

c. misrepresenting that INVOKANA was approved and deemed safe and effective for weight loss;

d. misrepresenting that INVOKANA was approved and deemed safe and effective for reducing blood pressure; and

e. misrepresenting INVOKANA's risk of unreasonable, dangerous, adverse side effects.

204. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

205. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public, including Decedent.

206. Defendants' misrepresentations were made before and at the time Defendants sold INVOKANA to Decedent.

207. Defendants' misrepresentations were made through various means, including but not limited to advertising material which stated "Greater Reductions in body weight"; and "Greater Reductions in systolic blood pressure," and prescribing information which failed to adequately warn of the risks presented by INVOKANA.

208. Defendants made these representations in furtherance of their aggressive and misleading marketing campaign with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of INVOKANA.

209. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Decedent, the truth regarding Defendants' claims that INVOKANA had been tested and found to be safe and effective for treating diabetes.

210. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

211. Defendants failed to exercise ordinary care in making their representations concerning INVOKANA and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of INVOKANA.

212. Defendants engaged in a nationwide marketing campaign, over-promoting INVOKANA in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of INVOKANA while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented INVOKANA's risk of unreasonable and dangerous adverse side effects, as well as its benefits.

213. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Decedent. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

214. But for Defendants' misrepresentations, Decedent would have avoided harm by choosing a safer alternative treatment.

215. After purchasing and subsequently ingesting INVOKANA, Decedent's kidneys were injured, causing renal failure and complications arising therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

216. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of

human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

217. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VIII
FRAUDULENT CONCEALMENT

218. Plaintiff restates the allegations set forth above as if fully rewritten herein.

219. Throughout the relevant time period, Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of INVOKANA.

220. Defendants fraudulently concealed information with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using INVOKANA;

b. Defendants represented that INVOKANA was safer than other alternative medications and fraudulently concealed information which demonstrated that INVOKANA was not safer than alternatives available on the market; and

c. Defendants downplayed, and concealed the risk of kidney injury by emphasizing only those with preexisting renal impairment were at risk of suffering a renal related adverse event, and by including key information in only the "Adverse Events" section, rather than the "Warnings and Precautions" section.

221. Defendants were under a duty to Decedent to disclose and warn of the defective and dangerous nature of INVOKANA because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of INVOKANA;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of INVOKANA from Decedent.

222. As the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, Defendants had unique knowledge and special expertise regarding INVOKANA. This placed them in a position of superiority and influence over Decedent and his healthcare providers. As such, Decedent and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

223. The facts concealed or not disclosed by Defendants to Decedent were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use INVOKANA.

224. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by INVOKANA was intentional, and the representations made by Defendants were known by them to be false.

225. The concealment of information and the misrepresentations about INVOKANA were made by Defendants in furtherance of their aggressive and misleading marketing campaign with the intent that doctors and patients, including Decedent, rely upon them so that Decedent would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA.

226. Decedent, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA

227. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Decedent and his physicians would not have prescribed or ingested the drug.

228. After purchasing and subsequently ingesting INVOKANA, Decedent's kidneys were injured, causing renal failure and complications arising therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

229. Defendants, by concealment or other action, intentionally prevented Decedent and his health care professionals from acquiring material information regarding the lack of safety of INVOKANA, thereby preventing Decedent from discovering the truth. As such, Defendants are liable for fraudulent concealment.

230. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

231. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IX
FRAUD

232. Plaintiff restates the allegations set forth above as if fully rewritten herein.

233. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Decedent, his prescribing health care professionals, the health care industry, and consumers that INVOKANA had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment, was approved and found to be safe and effective for weight loss, and was approved and found to be safe and effective for reducing blood pressure.

234. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of INVOKANA. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of INVOKANA, such as Decedent.

235. Defendants' fraudulent misrepresentations were made in furtherance of their aggressive and misleading marketing campaign with the intent of defrauding and deceiving the health care industry and consumers, including Decedent and his prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase INVOKANA, despite the risk of severe life threatening injury, which Defendants knew were caused by the products.

236. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks, and knowingly and intentionally misrepresented INVOKANA's approved indications.

237. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, including the permanence and likelihood of harm, which were known by Defendants to result from use of INVOKANA.

238. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with INVOKANA from physicians and patients, including Decedent and his prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the INVOKANA. For example:

a. INVOKANA was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of INVOKANA does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of the INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with INVOKANA was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. INVOKANA has not been approved and deemed safe and effective for weight loss;

f. INVOKANA has not been approved and deemed safe and effective for reducing blood pressure;

g. Defendants knew that the risks of harm associated with the use of INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies, such as Metformin, Onglyza, Januvia, and Jardiance, yet knowingly made material misrepresentations and omissions of fact on which Decedent relied when ingesting INVOKANA;

h. The limited clinical testing revealed that INVOKANA had an unreasonably high risk of injury, including Decedent's injuries, above and beyond those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

j. Defendants had knowledge of the dangers involved with the use of INVOKANA, which dangers were greater than those associated with other diabetes drug therapies;

k. Defendants intentionally and knowingly failed to disclose that patients using INVOKANA could suffer severe kidney damage and sequelae, and would require monitoring while treating with INVOKANA drug therapy; and/or

l. INVOKANA was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

239. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest INVOKANA, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

240. Defendants' intentional concealment and omissions of material fact concerning the safety of INVOKANA was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Decedent, and with reckless intent to mislead, so as to cause Decedent's prescribing health care professionals to purchase, prescribe, and/or dispense INVOKANA, and to cause Decedent to rely on Defendants' fraudulent misrepresentations that INVOKANA was a safe and effective diabetes drug therapy.

241. Defendants' fraudulent conduct as described herein was committed at the time Defendants submitted INVOKANA for approval, when Defendants introduced INVOKANA to U.S. consumers, and when Defendants directed advertisement and prescribing information containing false statements, misrepresentations and material omissions to the medical community and consumers, including Decedent.

242. Defendants, individually and collectively, in an effort to further their collective enterprise made the above false statements, misrepresentations and material omissions to Decedent, and Decedent's physicians.

243. At the time Decedent purchased and used INVOKANA, Decedent was unaware that Defendants had made misrepresentations and omissions, and instead Decedent reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of INVOKANA's safety and efficacy.

244. Defendants knew and had reason to know that INVOKANA could and would cause serious and potentially fatal personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

245. In reliance on Defendants' false and fraudulent misrepresentations, Decedent was induced to use and in fact used INVOKANA, thereby sustaining injuries and damages. Defendants knew or had reason to know that Decedent and his health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Decedent and his health care professionals would not have prescribed and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

246. During the marketing and promotion of INVOKANA to health care professionals, neither Defendants nor the co-promoters who were detailing INVOKANA on Defendants' behalf, warned health care professionals, including Decedent's prescribing health care professionals, that INVOKANA caused or increased the risk of harm of severe kidney damage.

247. Decedent reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of INVOKANA.

248. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Decedent, the public, Decedent's health care professionals, and the health care industry that INVOKANA was safe for use as a means of diabetes treatment, was approved and safe and effective for weight loss, and was approved and safe and effective for reducing blood pressure.

249. Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

250. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of INVOKANA, including Decedent. Defendants knew of INVOKANA's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

251. After purchasing and subsequently ingesting INVOKANA, Decedent's kidneys were injured, causing renal failure and complications therefrom, when INVOKANA's intended design forced significant amounts of unmetabolized glucose through Decedent's kidneys, leading to a blood-acid imbalance, placing further stress on Decedent's kidneys as his body attempted to cope with the effects of excess acid, and INVOKANA.

252. Defendants' conduct as described above was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

253. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Decedent suffered severe kidney injuries and other related health complications. In addition, Decedent required healthcare and services. Decedent incurred medical and related expenses. Until his death, Decedent also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages.

Decedent's direct medical losses and costs include physician care, monitoring, and treatment. Until his death, Decedent incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT X
(WRONGFUL DEATH)

254. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State, including but not limited to Indiana Code34-23-1-1.

255. Plaintiff brings this claim, where appropriate, on behalf of the Estate and for the benefit of the Decedent's lawful beneficiaries, including the surviving spouse.

256. At all times material hereto, Defendants owed a duty to Decedent to protect Decedent against reasonably foreseeable harms that a prudent person would anticipate were likely to result from the Defendants' acts or omissions as described in the preceding paragraphs.

257. Defendants breached that duty when they acted in the wrongful manner set forth in all preceding paragraphs above.

258. Defendants' wrongful conduct was the direct and proximate result of Decedent's death.

259. Defendants' conduct was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

260. As a direct and proximate result of the conduct of the Defendants and the defective nature of Invokana as outlined above, Decedent suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

261. As a direct and proximate cause of the conduct of Defendants, Plaintiff and Decedent's beneficiaries have suffered a pecuniary loss including but not limited to loss of support, loss of income of the Decedent, and said beneficiaries have been, continue to be and/or will in the future be deprived of his support, maintenance, guidance, love, affection, care and other services, and were all permanently damaged thereby.

262. As a direct and proximate cause of the conduct of Defendants, Decedent and his beneficiaries have incurred hospital, nursing and medical expenses, funeral and burial expenses and estate administration expenses as a result of Decedents' deaths. Plaintiff brings this claim on behalf of Decedent's lawful beneficiaries and surviving spouse for these damages and for all pecuniary losses under applicable state statutory and/or common laws, including but not limited to Indiana Code § 34-23-1-1.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT XI
(SURVIVAL ACTION)

263. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State of Indiana. This Count is plead alternatively to the Wrongful Death Count.

264. At all times material hereto, Defendants owed a duty to Decedent to protect Decedent against reasonably foreseeable harms that a prudent person would anticipate were likely to result from the Defendants' acts or omissions as described in the preceding paragraphs.

265. Defendants breached that duty when they acted in the wrongful manner set forth in all preceding paragraphs above.

266. Defendants' wrongful conduct was the direct and proximate result of Decedent's injuries.

267. As a direct and proximate result of the conduct of Defendants, where appropriate, Decedent, prior to death, was obligated to spend various sums of money to treat Decedent's injuries, which debts have been assumed by the Estate. As a direct and proximate cause of the aforesaid, Decedent was caused pain and suffering, mental anguish and impairment of the

enjoyment of life, until the date of Decedent's death; and, as a direct and proximate result of the aforesaid, Decedent suffered a loss of earnings and earning capacity. Plaintiff brings this claim on behalf of Decedent's estates under applicable state statutory and/or common laws, including but not limited to Indiana Code 34-9-3-1, *et seq*.

268. Defendants' conduct was committed with gross negligence and fraud and with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Decedent, thereby entitling Plaintiff to punitive damages in accordance with New Jersey law, and alternatively, Indiana law so as to punish Defendants and deter them from similar conduct in the future.

269. As a direct and proximate result of the conduct of Defendants, Decedent and Decedent's spouse and heirs, until the time of Decedent's death, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

270. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedent until the date of death, Plaintiff had and did continue to suffer permanent and ongoing psychological damage which may have required future psychological and medical treatment. Decedent's spouse as

264. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedent until the date of death, Plaintiff has and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Decedent's spouse, as Personal Representative of the estate of the Decedent, brings the claim on behalf of the estate and lawful heirs and in their own

right for damages under applicable state statutory and/or common laws, including but not limited to Indiana Code 34-9-3-1.

PRAYER FOR RELIEF

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

1. For general damages in an amount to be proven at the time of trial;
2. For special damages in an amount to be proven at the time of trial;
3. For statutory damages as set forth above, in an amount to be proven at the time of trial;
4. For exemplary and punitive damages against each and every Defendant in an amount to be proven at the time of trial, and sufficient to punish or deter Defendants and others from repeating the injurious conduct alleged herein;
5. For pre judgment and post judgment interest on the above general and special damages;
6. For costs of this suit and attorneys' fees; and
7. All other relief that this Court deems necessary, proper, and just.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

Respectfully Submitted,

THE LEVENSTEN LAW FIRM, PC

/s/ Michael W. Johnston

Dated: February 1, 2017

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Attorneys for Plaintiff

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Phyllis Craig, as Personal Representative :
of the Estate of John Reuben Craig

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michael W. Johnston, Esq., The Levensten Law Firm, P.C., 1420 Walnut Street, Suite 1500, Philadelphia, PA 19102

DEFENDANTS

Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC and Johnson & Johnson

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

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

TORTS

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

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

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

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

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

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

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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

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

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

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

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

PRISONER PETITIONS

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

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

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

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

Brief description of cause:
Failure to Warn, Fraud, Negligence

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
02/01/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Michael W. Johnston

FOR OFFICE USE ONLY

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

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