UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2750 Master Docket No. 3:16-md-2750
David Bottner, Plaintiff(s), vs. Janssen Pharmaceuticals Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC Defendants.	:	JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4 Civil Action No.: 3:18-cv-10449

COMPLAINT

Plaintiff(s) file this Complaint pursuant to CMO No. 4, and are to be bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiff(s), hereby designate the United States District Court for the Eastern District of Pennsylvania as the place of remand as this case may have originally been filed there.

David Bottner, (hereinafter "Plaintiff"), by and through undersigned counsel, brings this action seeking judgment against Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Janssen Ortho LLC and Johnson & Johnson (collectively referred to as Defendants) for injuries and damages caused by Plaintiff's ingestion of INVOKANA, a drug in the *gliflozin* class.

PARTIES

1. At all times relevant hereto, Plaintiff was a resident and citizen of Philadelphia, Pennsylvania, located in the County of Philadelphia County.

2. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as JANSSEN 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.

3. As part of its business, JANSSEN R&D is involved in the research, development, sales and marketing of pharmaceutical products, including INVOKANA.

4. Upon information and belief, and at all relevant times, JANSSEN R&D 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 diabetes medication.

5. Upon information and belief, defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICAL INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as JANSSEN PHARM) is a Pennsylvania corporation with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

6. As part of its business, JANSSEN PHARM is involved in the research development, sales, and marketing of pharmaceutical products, including INVOKANA.

7. JANSSEN PHARM is the holder of the New Drug Application (NDA) for INVOKANA.

8. Upon information and belief, and at all relevant times, JANSSEN PHARM 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 diabetes medication.

9. Upon information and belief, defendant JANSSEN ORTHO LLC (hereinafter referred to as JANSSEN 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. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

10. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products, including INVOKANA.

11. Upon information and belief, and at all relevant times, JANSSEN ORTHO was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug INVOKANA for use as a diabetes medication.

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

13. As part of its business, J&J, and its "family of companies," is involved in the research, development, sales, and marketing of pharmaceutical products, including INVOKANA.

14. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

15. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors 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.

16. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the drug INVOKANA.

JURISDICTION AND VENUE

17. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

18. Venue in this action properly lies in this judicial district pursuant to U.S.C. § 1391(b) because, at all times material hereto, a substantial part of the events or omissions giving rise to this claim occurred in this District, and 28 U.S.C. §1391(a) because at all times material hereto, Defendants JANSSEN and JOHNSON & JOHNSON had their principal place of business in this District, and all the defendants conducted substantial business in this District related to Invokana. Additionally, the Multi-District Litigation was created in and assigned to this District.

FACTUAL BACKGROUND

19. Plaintiff brings this case against Defendants for damages associated with ingestion of the pharmaceutical drug INVOKANA, which was designed, manufactured,

marketed, sold and distributed by Defendants. Specifically, Plaintiff suffered various injuries, physical pain and suffering, medical, hospital and surgical expenses as a direct result of using INVOKANA.

20. In March 2013, the United States Food and Drug Administration (FDA) approved Defendants' compound, *canagliflozin* (INVOKANA), for the treatment of type 2 diabetes, making Defendants' drug the first in its class to gain FDA approval.

21. *Canagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 (SGLT2) inhibitors, and is marketed in the United States by Defendants under the name INVOKANA.

22. Defendant J&J, the parent company of Janssen, is involved in the marketing and branding of Invokana, and publishes marketing and warnings regarding the product.

23. Defendants published advertisements on their company websites and issued press releases announcing favorable information about *Canagliflozin*. For example, the FDA's approval of *Canagliflozin* (INVOKANA) on March 29, 2013 was announced on the J&J website.

24. On March 14, 2016, J&J issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (*canagliflozin*)." The former announcements did not contain warnings about ketoacidosis, serious infections, while the latter announcement mentioned these conditions.

25. Defendant J&J also published information touting the strong sales of Invokana in its corporate reports and in earnings calls.

26. Further, J&J employees had responsibility for overseeing promotion strategies for the drug Invokana.

27. Materials including advertisements, press releases, website publications, and other communications regarding Invokana are part of the labeling of the drug, and could be altered without prior FDA approval.

28. Defendant J&J had the ability and the duty to improve the labeling of Invokana to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, amputations, etc.

29. Defendant J&J so substantially dominates and controls the operations of Janssen and Janssen R&D that it could have required them to make changes to the safety label of the drug Invokana.

30. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, and Janssen R&D.

31. In fact, J&J so substantially dominates and controls the operations of Janssen and Janssen R&D, that the entities are indistinct for purposes of this litigation such that Janssen and Janssen R&D should be considered agents or departments of J&J, and J&J is their alter-ego.

32. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing right to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in Pennsylvania and New Jersey and the remainder of the United States.

33. In February 2014, Janssen R&D submitted an NDA to the FDA for approval to market Invokana in the United States.

34. In August 2014, the FDA approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with Type 2 Diabetes.

35. As part of its marketing approval of *canagliflozin*, the FDA required the Defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; an enhanced pharmacovigilence program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamics study and a safety and efficacy study.

36. In an effort to increase sales and market share, Defendants have aggressively marketed and continue to aggressively market Invokana to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in Type I diabetics.

37. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Invokana, both as to its ability to lower glucose, and its benefit for non-surrogate measures of health, such as reducing adverse cardiovascular outcomes.

38. Defendants' marketing campaign willfully and intentionally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis, kidney failure, sepsis, amputation and other injuries.

39. Defendant JANSSEN PHARM acquired the marketing rights to INVOKANA in North America, and in collaboration with Defendant JANSSEN R&D, submitted INVOKANA's NDA for approval.

40. Defendant JANSSEN ORTHO manufactures INVOKANA for distribution to consumers throughout the United States, including Pennsylvania.

41. Upon information and belief, all Defendants participated in designing, developing, researching, manufacturing, marketing, distributing and selling INVOKANA.

42. INVOKANA is one of Defendants' top selling drugs, with annual sales exceeding $1 billion.

43. As part of their aggressive and misrepresentative marketing campaign for INVOKANA, Defendants have already paid at least $27 million to approximately 69,000 doctors to promote INVOKANA.

44. SGLT2 inhibitors, including INVOKANA, have FDA approval only for treating type 2 diabetes.

45. SGLT2 inhibitors, including INVOKANA, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, a significant portion of glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease, and exposes the drug's users to an increased risk of the injuries complained of herein.

46. In order to excrete glucose from the kidneys into the urinary tract, the kidneys must bind the glucose to a water molecule. This causes the body to excrete increased levels of water, leading to dehydration and ultimately causing hyopvolemia, a state of reduced blood volume, specifically a decreased level of blood plasma.

47. Hypovolemia is characterized by thickened and slower blood flow, which results in lower blood pressure and decreased perfusion of blood through the capillaries, a condition which is particularly acute in the extremities.

48. Blood carries platelets to the capillaries to heal wounds, and white blood cells to fight infection. Hypovolemia impairs both of these functions, making the body less able to heal from wounds, and to fight infections.

49. Individuals on INVOKANA are more likely to suffer injuries that cannot heal properly, and more likely to suffer infections that their body cannot fight, due to the dehydration-induced hypovolemia.

50. Once individuals develop infections in their feet or lower extremities, these infections can quickly spread to the bones, causing a condition known as osteomyelitis. The infections can also become gangrenous.

51. Once an infection has spread to the bone or become gangrenous, the only safe medical treatment for the patient is amputation.

52. Because INVOKANA prevents patients from using a significant amount of the body's primary fuel, glucose, their bodies turn to fat as an alternate source of energy. As the body begins to breakdown fat, acids called ketones are introduced into the body's blood stream, creating the potential for acidosis- excessive blood acidity.

53. Generally, when a person is suffering from ketoacidosis- excess ketones in the blood, they also report high blood-glucose levels, and frequent urination.

54. Normally, the body excretes excess ketones through urination in order to obtain proper blood-acid balance; however, because INVOKANA places the kidneys under duress by expelling significant amounts of glucose that has not been metabolized through the urinary tract, INVOKANA users are often unable to obtain blood-acid balance without medical intervention.

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

need, but INVOKANA forces this very same emergency process on its users as its primary course of treatment- daily.

56. Though INVOKANA is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market INVOKANA for off label purposes, including, but not limited to, weight loss and reduced blood pressure.

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

58. One of the effects of the increased elimination via urination is volume contraction in the blood, which can reduce blood flow and thicken the blood plasma, creating circulation problems in the lower extremities.

59. As circulation in the extremities worsens, the body is less able to heal and fight infections, which increases the risk of ulcers, and can lead to dangerous infections that may spread into the bones.

60. On January 10, 2013, the FDA Endocrinologic and Metabolic Drugs Advisory Committee noted that in the first thirty days of use, INVOKANA had a cardiovascular event Hazard Ratio of 6.9, i.e., that patients who were taking INVOKANA had a 690% higher likelihood of suffering a cardiovascular event, including heart attack, than those taking a placebo.

61. Due to concerns about the increased risk of cardiovascular events, the FDA instructed Defendants to conduct a long-term study to assess the potential cardiovascular risks of INVOKANA. As a result, the Defendants developed the CANVAS trial, a large study of

thousands of individuals, comparing individuals on INVOKANA versus individuals receiving a placebo treatment.

62. On May 15, 2015, the FDA issued a Public Health Advisory linking SGLT2 inhibitors, including INVOKANA, to diabetic ketoacidosis, a condition which can result in organ failure and even death.

63. The FDA has also received a significant number of adverse event reports linking INVOKANA to kidney injuries, including renal failure, renal impairment, renal insufficiency and renal infection.

64. In December, 2015, the FDA required Defendants to change the INVOKANA warning label to warn of ketoacidosis and urosepsis- a severe, life-threatening bacterial infection of the blood which can injure the kidneys.

65. In June, 2016, the INVOKANA warning label was changed to include kidney failure warning.

66. In August, 2016, the INVOKANA warning label was changed to include reports of "fatal" diabetic ketoacidosis.

67. In February 2017, the INVOKANA warning label was changed to include more detailed warnings on diabetic ketoacidosis and acute kidney injury.

68. In May 2017, the FDA issued a Drug Safety Communication indicating there was evidence of a causal relationship between INVOKANA and an increased risk of amputations.

69. In June 2017, the CANVAS study was published, which showed a INVOKANA had an amputation Hazard Ratio of 1.97 versus placebo, that patients taking INVOKANA were nearly twice as likely to suffer an amputation as those with *uncontrolled* diabetes.

70. In July 2017, the INVOKANA warning label was changed to include a black box warning on the risk of amputation.

71. Since INVOKANA's release, the FDA has received a significant number of reports of severe kidney damage among users of INVOKANA.

72. An analysis of the FDA adverse event database shows that patients taking INVOKANA are several times more likely to report severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

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

74. Despite their knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis, kidney failure, stroke, heart attack, and infections requiring amputation, Defendants promoted and marketed Invokana as safe and effective for persons such as Plaintiff throughout the United States, including Pennsylvania and New Jersey.

75. Though Defendants did nothing to alert United States consumers, and health care professionals of the risks associated with INVOKANA, they did send "Dear Doctor" letters warning of INVOKANA's ketoacidosis risk to healthcare professionals in Canada and Australia in July, 2015, after those countries' respective drug regulatory agencies issued safety announcements concerning INVOKANA. No such letter was sent to Plaintiff's healthcare providers.

76. Despite clear signals in the available data, Defendants did not tell consumers, healthcare professionals, or the scientific community about the dangers of INVOKANA.

77. Defendants' original and in some respects, current labeling and prescribing information:

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

b. Failed to provide adequate warnings, about the true safety risks associated with the use of INVOKANA;

c. Failed to disclose the need to monitor ketones;

d. Failed to warn that ketoacidosis can occur absent typical symptoms, such as high blood-glucose;

e. Failed to include a warning about ketoacidosis, and its life threatening propensities, associated with INVOKANA;

f. Failed to include a warning about increased risk of amputations associated with INVOKANA;

g. Failed to include a **"BOXED WARNING"** about renal failure, renal impairment, renal insufficiency and renal infection events associated with INVOKANA;

h. Failed to include a **"BOLDED WARNING"** about renal failure, renal impairment, renal insufficiency and renal infection events associated with INVOKANA;

i. Failed to include a **"BOXED WARNING"** about the risk of cardiovascular injury, including heart attack and stroke, associated with INVOKANA; and

j. Failed to include a **"BOLDED WARNING"** about the risk of cardiovascular injury, including heart attack and stroke, associated with INVOKANA.

78. Consumers, including Plaintiff, who have used INVOKANA for treatment of diabetes, have several alternative safer products available for treatment. SGLT-2 inhibitors, including INVOKANA, are the only class of drugs which utilize the mechanism of expelling significant quantities of glucose through the kidneys to lower blood-glucose.

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

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

81. Consumers of Invokana and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, sepsis, cardiovascular problems, stroke, amputations and the life-threatening complications thereof.

82. Plaintiff had several alternative and safer methods to treat his diabetes, including diet, exercise and other diabetes medications.

83. As a direct result, in May 2016, Plaintiff was prescribed and began taking INVOKANA, primarily to treat diabetes.

84. Plaintiff ingested and used INVOKANA as prescribed and in a foreseeable manner.

85. The INVOKANA used by Plaintiff was provided to him/her in a condition substantially the same as the condition in which it was manufactured and sold.

86. Plaintiff agreed to initiate treatment with INVOKANA in an effort to reduce his/her blood sugar. In doing so, Plaintiff relied on claims made by Defendants that INVOKANA was safe and effective for the treatment of diabetes.

87. Instead, INVOKANA can cause severe injuries, including heart attack, stroke, renal failure, renal impairment, renal insufficiency, kidney injury, diabetic ketoacidosis and amputations.

88. After beginning treatment with INVOKANA, and as a direct and proximate result thereof, on or about January 18, 2018, Plaintiff suffered from an amputation of the fifth toe, including the metatarsal head, of the left foot, and on or about February 20, 2018, Plaintiff suffered from an amputation of the remaining portion of the fifth metatarsal of the left foot.

89. As a result of his/her injuries, Plaintiff was hospitalized and/or required substantial medical treatment.

90. At the time of Plaintiff's injuries, Plaintiff regularly ingested the INVOKANA as prescribed by his/her doctor.

91. Defendants knew, or should have known, the risks associated with the use of INVOKANA, including the risk of lower extremity amputations.

92. The development of Plaintiff's injuries was 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 Plaintiff's injuries.

93. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's defects.

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

95. Plaintiff would not have used INVOKANA had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with INVOKANA, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA.

96. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his/her physicians the true and significant risks associated with ingesting INVOKANA.

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

98. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has 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.

99. Plaintiff has suffered from mental anguish from the knowledge that he/she may suffer life-long complications as a result of the injuries caused by INVOKANA.

COUNT I
STRICT LIABILITY

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

101. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug INVOKANA was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

102. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed INVOKANA, including the INVOKANA used by Plaintiff, which was in a defective and unreasonably dangerous condition.

103. Defendants expected INVOKANA to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

104. At all times relevant hereto, Defendants' INVOKANA was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

105. At all times relevant to this action, INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes;

c. INVOKANA was insufficiently tested;

d. INVOKANA caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time INVOKANA was marketed and sold that ingestion of INVOKANA would result in an increased risk of heart attack, renal failure, renal impairment, renal insufficiency, ketoacidosis, amputation and other severe injuries;

f. Inadequate post-marketing surveillance;

g. There were safer alternative designs and formulations that were not utilized; and

h. Inadequate warnings or instructions, as the Defendants knew, or should have known, that the product created a risk of serious and dangerous side effects, including kidney injuries, heart attack, stroke, and diabetic ketoacidosis, amputation, as well as other severe and personal injuries.

106. INVOKANA was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

107. INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with INVOKANA's design or formulation.

108. INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

109. At all times relevant to this action, Defendants knew, or had reason to know, that INVOKANA was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

110. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that INVOKANA was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

111. When Defendants placed INVOKANA into the stream of commerce, they knew it would be prescribed to treat diabetes, and they marketed and promoted INVOKANA as safe for treating diabetes.

112. Plaintiff was prescribed, purchased, and used INVOKANA. Plaintiff used INVOKANA for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

113. Neither Plaintiff nor his/her health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with INVOKANA before Plaintiff's ingestion of INVOKANA.

114. The harm caused by INVOKANA far outweighed its benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed INVOKANA to make it less dangerous. When Defendants designed INVOKANA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

115. At the time INVOKANA left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without substantially impairing the reasonably anticipated or intended function of INVOKANA. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

116. At all times relevant, Defendants knew, or should have known, that the warnings or instructions for INVOKANA were inadequate to warn of the nature, likelihood or severity of the risks associated with the drug.

117. Defendants' defective design of INVOKANA was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of INVOKANA.

118. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of INVOKANA.

119. The defects in INVOKANA were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

120. Due to the unreasonably dangerous condition of INVOKANA, Defendants are liable for Plaintiff's injuries.

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

122. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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
MANUFACTURING DEFECT

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

124. INVOKANA was designed, manufactured, marketed, promoted, sold and introduced into the stream of commerce by Defendants.

125. When it left the control of Defendants, INVOKANA was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

126. INVOKANA was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from the product specifications and/or applicable requirements and posed a risk of serious injury and death.

127. Specifically, INVOKANA was more likely to cause serious injuries, including heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputations, than other diabetes medications.

128. Plaintiff used INVOKANA in substantially the same condition it was in when it left the control of Defendants and any changes or modifications were foreseeable by Defendants.

129. Plaintiff or his/her healthcare providers did not misuse or materially alter their INVOKANA.

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

131. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injury. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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 III
DESIGN DEFECT

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

133. 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 Plaintiff.

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

135. INVOKANA was in an unsafe, defective and inherently dangerous condition.

136. INVOKANA contains defects in its design which render the drug dangerous to consumers, such as Plaintiff, 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, heart attack, renal failure, renal impairment, renal insufficiency ketoacidosis and amputations.

137. 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.

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

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

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

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

142. 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 Plaintiff expected.

143. The intended or actual utility of INVOKANA is not of such benefit or to justify the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation.

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

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

146. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, 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.

147. The unreasonably dangerous nature of INVOKANA caused serious harm to Plaintiff.

148. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition,

Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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 IV
FAILURE TO WARN

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

150. Defendants had a duty to warn Plaintiff and his/her healthcare providers regarding the nature, likelihood, and severity of risks associated with INVOKANA, including, but not limited to, heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputations.

151. Defendants' knew, or in the exercise of reasonable care, should have known about the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputations.

152. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of heart attack, stroke, renal

failure, renal impairment, renal insufficiency, ketoacidosis and amputation, in light of the likelihood that its product would case these injuries.

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

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

155. When it left Defendants' control, INVOKANA was defective and unreasonably dangerous for failing to adequately warn of the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation.

156. Plaintiff used INVOKANA for its approved purpose and in a manner normally intended and reasonably foreseeable by Defendants.

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

158. Defendants, as the manufacturers and distributors of INVOKANA, are held to the level of knowledge of an expert in the field.

159. The warnings that were given by Defendants failed to properly warn physicians of the risks associated with INVOKANA, subjecting Plaintiff to risks that exceed the benefits to the Plaintiff. Plaintiff, individually and through his/her physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants.

160. Defendants had a continuing duty to warn Plaintiff and his/her prescriber of the dangers associated with INVOKANA.

161. Had Plaintiff or his/her healthcare provider received adequate warnings regarding the risks associated with the use of INVOKANA, Plaintiff would not have used it.

162. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with 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. Defendants' outrageous conduct warrants an award of punitive damages.

163. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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 V
NEGLIGENCE

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

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

166. The Defendants owed Plaintiff 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 Plaintiff and other consumers of the dangers associated with INVOKANA.

167. 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.

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

169. 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 Plaintiff.

170. 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 Plaintiff.

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

172. Defendants knew that many health care professionals were prescribing INVOKANA and that many patients developed serious side effects including, but not limited to, heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation.

173. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, supplying, promotion, marketing, advertisement, packaging, 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 heart attack, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation, and failed to prevent or adequately warn of the severity of these risks and injuries.

174. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, 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.

175. 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 Plaintiff, 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 INVOKANA induced heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation;

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.

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

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

178. Defendants' negligence was the proximate cause of the injuries, harm and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

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

180. As a foreseeable, direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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
BREACH OF EXPRESS WARRANTY

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

182. 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.

183. Defendants expressly represented to Plaintiff, other consumers, Plaintiff'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. did not produce any dangerous and life threatening side effects; and

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

184. 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.

185. Defendants advertised, labeled, marketed and promoted INVOKANA, representing the quality to health care professionals, Plaintiff 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.

186. Despite this, Defendants expressly represented that INVOKANA was safe and effective, that it was safe and effective for use by individuals such as Plaintiff and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and his/her 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.

187. In particular the Consumer Medication Guide did not include any language that would suggest Invokana has been associated with diabetic ketoacidosis, stroke, heart attack, kidney failure, blood infections, kidney infections or amputation.

188. 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.

189. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects and causes severe and permanent injuries. Therefore, Defendants breached the aforementioned warranties.

190. 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.

191. Neither Plaintiff nor his/her prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning INVOKANA.

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

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

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

195. As a foreseeable, direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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
BREACH OF IMPLIED WARRANTY

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

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

198. 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.

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

200. 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 lower extremity amputations.

201. At all relevant times, Defendants intended that INVOKANA be used in the manner used by Plaintiff, 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.

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

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

204. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

205. Plaintiff 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.

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

207. Plaintiff and his/her physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

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

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

210. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

211. 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.

212. Neither Plaintiff nor his/her health care professionals reasonably could have discovered or known of the risk of serious injury associated with INVOKANA.

213. Defendants' breach of these implied warranties caused Plaintiff's injuries.

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

215. As a foreseeable, direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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
NEGLIGENT MISREPRESENTATION

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

217. 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.

218. 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.

219. 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.

220. 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 Plaintiff.

221. 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.

222. 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 regarding the safety of INVOKANA. Defendants made material misrepresentations to Plaintiff, his/her 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; and

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

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

224. 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.

225. Defendants made these representations with the intent to induce reliance thereon and to encourage the prescription, purchase and use of INVOKANA.

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

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

228. 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.

229. 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.

230. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. 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.

231. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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
FRAUDULENT MISREPRESENTATION

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

233. Defendants intentionally and fraudulently misrepresented the safety and efficacy of INVOKANA in the product label.

234. Specifically Defendants intentionally and fraudulently:

a. Provided a "Warnings and Precautions" section of the INVOKANA prescribing information that purports to expressly describe the relevant and material potential side-effects that Defendants knew, or should have known, about, but in which material and relevant information was fraudulently withheld from this section;

b. Provided Consumer Medication Guide that expressly indicates "What is the most important information I should know about INVOKANA?", "What are the possible side effects of INVOKANA?", "General information about the safe and effective use of INVOKANA" and fraudulently omits information INVOKANA has been associated with diabetic ketoacidosis, amputation, kidney failure, stroke or cardiovascular events;

c. On information and belief, each and every advertisement and marketing channel fraudulently omits information about the risks of INVOKANA and overstates the benefits;

d. Failed to disclose that INVOKANA was not as safe and effective as other diabetes drugs;

e. Failed to disclose that INVOKANA does not result in safe and more effective diabetes treatments than other available drugs;

f. Failed to disclose that the risk of harm associated with INVOKANA was greater than the risk of harm associated with other diabetes drugs;

g. Failed to disclose that Defendants knew that INVOKANA was not adequately tested;

h. Failed to disclose that testing had revealed unreasonably high risk of injury;

i. On information and belief, failed to disclose that Defendants intentionally withheld safety information from the FDA; and

j. Affirmatively asserted that INVOKANA was safe and effective.

235. 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 Plaintiff, other consumers, Plaintiff's physicians and the medical community.

236. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and his/her physicians, rely upon them.

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

238. Defendants J&J, Janssen and Janssen R&D, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug INVOKANA was generally well tolerated and safe for use and was not likely to cause side effects other than the ones listed – these listed side effects did not include diabetic ketoacidosis,

renal injury or renal failure, stroke, cardiovascular events or infections that may lead to amputations. Plaintiff, his/her doctors, and other relied upon these representations.

239. As a foreseeable, direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered from an amputation of the fifth toe, including the metatarsal head, of the left foot on or about January 18, 2018, an amputation of the remaining portion of the fifth metatarsal of the left foot on or about February 20, 2018, and other related health complications. Plaintiff has incurred medical and related expenses. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, mental and physical pain and suffering as well as the injuries and damages alleged herein.

COUNT X
UNJUST ENRICHMENT

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

241. Plaintiff conferred a benefit on Defendants by purchasing INVOKANA.

242. Plaintiff, however, did not receive a safe and effective drug for which he/she paid.

243. It would be inequitable for the Defendants to retain this money, because Plaintiff did not, in fact, receive a safe and efficacious drug.

244. By virtue of the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of the Defendants' wrongful profits, revenue and benefits to the extent, and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT XI
FRAUD

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

246. Defendants intentionally, willfully, knowingly and fraudulently misrepresented to Plaintiff, his/her 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.

247. 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 Plaintiff.

248. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and his/her 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 product.

249. 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.

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

251. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with INVOKANA from physicians and patients, including Plaintiff and his/her 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. 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, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff relied when ingesting INVOKANA;

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

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

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

i. Defendants intentionally and knowingly failed to disclose that patients using INVOKANA could suffer heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis, amputation and sequelae; and

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

252. Defendants made the above misrepresentations before, during and after FDA approval of INVOKANA, and to date, continue to make such misrepresentations.

253. Defendants' misrepresentations were made through various methods, including, but not limited to, INVOKANA's published labeling and medication guide, medical literature, promotional materials directed at consumers, promotional materials directed at health care professionals and documentation submitted in support of INVOKANA's NDA.

254. 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.

255. 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 Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's prescribing health care professionals to purchase, prescribe and/or dispense INVOKANA, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that INVOKANA was a safe and effective diabetes drug therapy.

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

257. Defendants knew and had reason to know that INVOKANA could and would cause serious 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.

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

259. 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 Plaintiff's prescribing health care professionals, that INVOKANA caused or increased the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis and amputation.

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

261. Defendants willfully, wrongfully and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals and the health care industry that INVOKANA was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed and suppressed the true results of Defendants' clinical tests and research.

262. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. 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.

263. As a foreseeable, direct and proximate consequence of Defendants' actions, omissions and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires, and will continue to require, healthcare and services. Plaintiff has incurred, and will continue to incur, medical and related expenses. Plaintiff also has suffered, and will continue to suffer, 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. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred, and will continue to incur, 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 XII
VIOLATION OF CONSUMER PROTECTION LAWS

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

265. Plaintiff used INVOKANA and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protections laws.

266. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have:

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

267. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of INVOKANA.

268. Defendants uniformly communicated the purported benefits of INVOKANA while failing to disclose the serious and dangerous side effects related to the use of INVOKANA and of the true state of INVOKANA's regulatory status, its safety, its efficacy and its usefulness. Defendants made these representations to physicians, the medical community at large and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

269. Defendants' conduct in connection with INVOKANA was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous materiel facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of INVOKANA.

270. As a result of these violations of consumer protection laws, Plaintiff have incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

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.

PUNITIVE DAMAGES ALLEGATIONS

271. Plaintiffs adopt by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

272. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and more specifically the serious side effects and/or complications associated with INVOKANA.

273. In respect to the FDA, physicians and consumers, Defendants downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of INVOKANA, despite available information that INVOKANA was likely to cause serious side effects and/or complications.

274. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure to warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

275. Defendants were, or should have been, in possession of evidence demonstrating that INVOKANA causes serious side effects. Nevertheless, Defendants continued to market INVOKANA by providing false and misleading information with regard to safety and efficacy.

276. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing INVOKANA to consumers, from purchasing and consuming INVOKANA, thus

depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming INVOKANA.

277. The acts, conduct and omissions of Defendants, as alleged throughout this Complaint were wanton, willful, fraudulent, dishonest and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other INVOKANA users and for the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

278. Prior to the manufacturing, sale and distribution of INVOKANA, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience, and did experience, severe physical, mental and emotional injuries. Further, Defendants, through their officers, directors, managers and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using INVOKANA.

279. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in INVOKANA and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in INVOKANA. Defendants and their agents, officers and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of INVOKANA knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and

monetary profits. Said conduct was motivated by the reprehensible motive of increasing monetary profits for the sale of INVOKANA.

280. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

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.

[THIS SPACE INTENTIONALLY LEFT BLANK]

PRAYER FOR RELIEF

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

1. Judgment for Plaintiff and against Defendants;
2. Damages to compensate Plaintiff's injuries sustained as a result of the use of INVOKANA for past and future loss of income proven at trial;
3. Physical pain and suffering of the Plaintiff and any and all damages allowed under the law;
4. Pre and post judgment interest as the lawful rate;
5. Exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;
6. A trial by jury on all issues of the case; and
7. For any other relief as this court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied including, but not limited to, reasonable attorneys' fees and costs and expert fees.

DEMAND FOR A TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues and defenses.

RESPECTFULLY SUBMITTED,

Dated: 06/12/2018

/s/ *Thomas A. Taylor*
Attorney for Plaintiff

Timothy M. O'Brien, Esq. (FL Bar No. 055565)
Thomas A. Taylor, Esq. (FL Bar No. 0125308)
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tobrien@levinlaw.com
ataylor@levinlaw.com
Attorneys for Plaintiffs

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

Case No. 3:18-cv-10449

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

DAVID BOTTNER,

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

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*

Timothy M. O'Brien & Thomas A. Taylor
Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
316 S. Baylen Street, 6th Floor, Pensacola, FL 32502
850-435-7084; tobrien@levinlaw.com; ataylor@levinlaw.com

DEFENDANTS

JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH & DEVELOPMENT LLC, JOHNSON & JOHNSON, ET AL.

County of Residence of First Listed Defendant Mercer
(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
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability

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 BRIAN MARTINOTTI DOCKET NUMBER MDL No. 2750

DATE 06/12/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Thomas A. Taylor

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

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

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

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

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

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