UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION Robin Boren, Plaintiff, vs. Janssen Pharmaceuticals Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC Defendants	MDL 2750 Master Docket No. 3:16-md-2750 JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN **DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4** Civil Action No.: 3:18-cv-14519

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff files this Complaint pursuant to CMO No. 4, and is to be bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiff, hereby designates the United States District Court for the Eastern District of Texas as the place of remand as this case may have originally been filed there.

Plaintiff, Robin Boren, by and through undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA (at times referred to herein as “the subject product”) for the treatment of diabetes.

2. Defendants Janssen Pharmaceuticals ("JANSSEN"), Johnson & Johnson, Co. ("JOHNSON & JOHNSON"), concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, Robin Boren, other consumers, and the medical community.

3. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including amputation.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff had a toe amputation. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff.

5. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

6. At all relevant times Plaintiff ROBIN BOREN and spouse, KIM BOREN, were citizens and residents of Little Elm, Texas located in Denton County.

7. Plaintiff began taking INVOKANA on or about January 2016 and continued to use INVOKANA until about April 2017. As a result of ingesting INVOKANA, Plaintiff suffered amputation of his right big toe on October 2, 2016 Medical City Plano in the city of Plano state of Texas.

8. Defendant JANSSEN is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN is registered to do business in Texas and has designated a registered agent in Texas. JANSSEN is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

9. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

JURISDICITION

10. 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.

11. Venue in this action properly lies in this judicial district pursuant to 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 Defendants conducted substantial business in this district.

FACTUAL BACKGROUND

12. This action seeks, among other relief, general and special damages due to Plaintiff Robin Boren suffering severe, life threatening, and permanently debilitating side effect[s] of an amputation caused by Invokana.

13. Invokana also known as canagliflozin, is a member of gliflozin class of pharmaceuticals also known as sodium glucose co-transporter 2 ("SGLT2") inhibitors.

14. SGLT2 inhibitors, including Invokana, inhibit renal glucose reabsorption through the SGL2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract instead of reabsorbed into the blood stream thereby putting additional strain on the kidneys.

15. SGLT2 inhibitors, including Invokana, are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose cotransporter receptors, including SGLT1.

16. The SGLT2 and SGLT1 receptors are located throughout the body, including in the kidney, intestines, and brain.

17. The active ingredient in Invokana, canagliflozin is contained in both Invokana and Invokamet and has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States. This makes it unique among the class of SGLT2 inhibitors.

18. SGLT2 inhibitors, including Invokana, are currently approved only for improvement of glycemic control in adults with type 2 diabetes.

19. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing,

producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Invokana for the use and application by patients with diabetes, including, but not limited to, Robin Boren.

20. 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.

21. 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 web site.

22. On March 1, 2013, Defendants announced the approval of Canagliflozin (Invokana) in the United States as a new treatment option for Type 2 diabetes. 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 announcement did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions. Neither announcement contained any warnings about the increased risk of amputations.

23. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities nationally including towards residents of Louisiana and New Jersey.

24. The Invokana-related pages on the Defendants' web sites are accessible from within Louisiana and New Jersey and have been indexed by search engines so that they are located through searches that are conducted from within Louisiana and New Jersey.

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, web site 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 infections such as urosepsis as well as gangrene leading to amputations.

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

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 Louisiana, 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 pharmacovigilance 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 1 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. Invokana is one of Defendants' top selling drugs, with annual sales exceeding $1 billion.

40. In September 2015, the FDA announced that SGLT2 inhibitors cause premature bone loss and fractures.

41. In December 2015, the FDA announced that SGLT2 inhibitors cause diabetic ketoacidosis, pyelonephritis (kidney infections), and urosepsis.

42. In May 2016, the FDA announced that SGLT2 inhibitors have been linked to an increased risk of amputations.

43. In June 2016, the FDA announced that SGLT2 inhibitors cause severe renal impairment, angioedema, and anaphylaxis.

44. In May of 2017 the FDA confirmed that Invokana and Invokamet increase the risk of leg and foot amputations and required a black box warning, as well as announcing further investigation into this safety issue.

45. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Robin Boren.

46. Defendants, both individually and in concert with one another, misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to

debilitating and/or life-threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, sepsis and kidney failure and its sequelae and amputations of the toes, feet and legs.

47. Specifically, Defendants knew or should have known of the risks of diabetic ketoacidosis and kidney failure based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports, and regulatory authority investigations, including, but not limited to the following:

    a. Canagliflozin selectivity for the SGLT1 receptor;
    b. Animal studies demonstrating increased ketones when given canagliflozin;
    c. Studies of SGLT1 inhibitor phlorizin, and its propensity to cause ketoacidosis;
    d. Reports involving people with familial glycosuria, an indication of a propensity to develop ketoacidosis;
    e. Clinical studies demonstrating increases in glucagon in people taking canagliflozin;
    f. Clinical studies, adverse event reports, and case reports demonstrating increased ketones in people taking canagliflozin;
    g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and volume depletion in people taking canagliflozin;
    h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking canagliflozin;

i. Clinical studies, adverse event reports and case reports demonstrating re-challenge responses in increasing Ketones and diabetic ketoacidosis in people taking Canagliflozin;

j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking canagliflozin compared to other glucose lowering medications.

k. Clinical studies and adverse event reports demonstrating an increased rate of reports of patients developing gangrene, diabetic foot ulcers, lower limb ischemia and running the risk of and/or actually requiring an amputation.

48. Diabetic ketoacidosis may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma.

49. Amputations lead to loss of mobility further exacerbating the risks of a sedentary lifestyle, including but not limited to weight gain, cardiovascular risks, pressure ulcers and resulting dangerous infections, as well as the physical and economic requirements of adapting to life in a wheelchair, such as ramps, bathroom and kitchen alterations, the inability to drive or costs needed for vehicle adaptations, cost for prosthetics and impaired earning potential.

50. Invokana induced diabetic ketoacidosis may lead to delayed treatment because in many cases Invokana will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis. This may result in increased progression of the condition and increased injury to the patient.

51. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system. They were also aware that Invokana use causes volume depletion and that, as with thiazide diuretics, this could lead to increased risk of gangrene, diabetic foot ulcers, lower limb ischemia and eventually amputation of toes, feet and legs below the knee.

52. On June 12, 2017 the New England Journal of Medicine published results from the Canagliflozin Cardiovascular Assessment Study ("CANVAS") which integrated data from two trials involving a total of 10,142 patients. CANVAS reported that the risk of lower limb amputations was 5.9 amputations per 1.000 patients per year for canagliflozin compared to 2.8 amputations per 1,000 patients per year for placebo. Defendants, who sponsored and supported CANVAS, received and were aware of this data well before the publication date. Yet, despite this knowledge, they failed to make any changes to their label and failed to alert patients like Plaintiff and their physicians of this serious risk.

53. Despite their knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis, kidney failure and amputations, Defendants promoted and marketed Invokana as safe and effective for persons such as Robin Boren throughout the United States, including Texas.

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

55. Defendants failed to adequately warn consumers and physicians about the risks associated with Invokana and the monitoring required ensuring their patients' safety.

56. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not conduct the necessary additional studies to properly evaluate these risks prior to marketing the drug to the general public.

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

SPECIFIC ALLEGATIONS

58. Robin Boren had several alternative and safer methods to treat his diabetes, including diet and exercise and other diabetes medications. Robin Boren was prescribed Invokana on or about January 2016 and used it as directed.

59. In January 2016 Robin Boren was prescribed Invokana to be taken once by mouth daily to improve glycemic control as an adjunct to diet and exercise.

60. In or about approximately March 2016, as a direct result of his treatment with Invokana, Robin Boren developed diabetic ulcers on his right foot.

61. In or about March 2016 through December 2016, as a direct result of his treatment with Invokana, Robin Boren began wound care for treatment of the diabetic ulcers and infections.

62. In or about October 2016 through December 2016, as a direct result of his use of Invokana, Robin Boren underwent surgeries for amputations of his right big toe.

63. Plaintiff now has constant pain and limited mobility as a result of Invokana usage.

64. Robin Boren has endured pain and suffering and will continue to endure pain and suffering as a result of his permanent disability, as well as emotional distress, loss of

enjoyment of life, and economic loss, including significant expenses for medical care and treatment. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

65. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused Robin Boren's permanent injuries and damages.

66. Robin Boren's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life threatening and debilitating risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. The conduct and the product defects were a substantial factor in bringing about Plaintiff's injuries.

67. Defendants had a duty to warn Robin Boren's prescribing physicians about the risks of Invokana use, including the risk of diabetic ketoacidosis, renal failure, sepsis, resulting complications thereof as well as gangrene, diabetic foot ulcers, lower limb ischemia and amputations. Had Robin Boren and his physicians known the risks associated with the use of SGLT2 inhibitors, including Invokana, Robin Boren would not have been prescribed Invokana, would not have taken Invokana, and/or he would have been adequately monitored for its side effects, an as a result, would not have suffered injuries and damages from using Invokana.

68. Robin Boren's prescribing and treating physicians relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Robin Boren's prescribing and treating physicians directly, through sales representatives detailing the product, print and television advertising, articles and study reports funded and promoted by Defendants, and

indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through their comprehensive marketing campaigns.

69. Robin Boren relied on claims made by defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Robin Boren directly, through print and television advertising, and indirectly, through his healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

70. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Robin Boren made an independent decision to use Invokana in reference to the overall benefits and risks communicated by Defendants.

71. Robin Boren's injuries were a reasonable foreseeable consequence of Defendants' conduct and Invokana's hazards, and were not reasonably foreseeable to Plaintiff or Plaintiff's physicians.

DELAYED DISCOVERY

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

73. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

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

75. Each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

COUNT I
PRODUCT LIABILITY ACT — MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1, *et seq*.)

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

77. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling INVOKANA.

78. At all times material to this action, INVOKANA was expected to reach, and did reach, consumers in the State of Texas and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

79. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, INVOKANA contained manufacturing defects which rendered the subject product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

c. The subject product was not made in accordance with Defendants' specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of Defendants.

e. The subject product manufactured and/or supplied by Defendants was not reasonably fit, suitable or safe for its intended purpose because when it left Defendants' hands, it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae. In particular, the product is not safe, has numerous and serious side effects, and causes severe and permanent injuries including, but not limited to, developing severe kidney damage and risk of amputation.

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 II
PRODUCT LIABILITY ACT — DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, et seq.)

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

81. INVOKANA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

82. At all times material to this action, INVOKANA was expected to reach, and did reach, consumers in the State of Texas and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

83. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

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 subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing severe kidney damage and other serious injuries and side effects;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making the use of INVOKANA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes;

c. The design defects of INVOKANA existed before it left the control of Defendants;

d. INVOKANA was insufficiently and inadequately tested;

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

f. INVOKANA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the

risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

84. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

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

COUNT III
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, et seq.)

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

86. INVOKANA was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing severe kidney damage and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for type 2 diabetes. Thus, the subject

product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

87. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

88. Plaintiff was prescribed and used the subject product for its intended purpose.

89. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

90. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

91. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

92. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

93. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, severe kidney damage, diabetic ketoacidosis, stroke, and heart attack.

94. Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

95. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

96. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

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

COUNT III
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, et seq.)

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

98. INVOKANA was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing severe kidney damage and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for type 2 diabetes. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq*.

99. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

100. Plaintiff was prescribed and used the subject product for its intended purpose.

101. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

102. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

103. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

104. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

105. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, severe kidney damage, diabetic ketoacidosis, stroke, and heart attack.

106. Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

107. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

108. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

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

COUNT IV
BREACH OF EXPRESS WARRANTY

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

110. Defendants expressly represented to Plaintiff, other consumers, and the medical community that INVOKANA was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

111. 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, including, but not limited to, developing severe kidney damage and other serious injuries and side effects.

112. At the time of the making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of Defendants.

113. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

114. 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.

115. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

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

COUNT V
BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

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

117. Defendants warrant, as a matter of law, that the subject product is reasonably fit for its ordinary and intended use.

118. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing severe kidney damage and other serious injuries and side effects. As a result, INVOKANA is unfit and inherently dangerous for ordinary use.

119. As a direct and proximate result of Defendants' actions, Plaintiff suffered amputation of his right big toe. Plaintiff has and will sustain significant injuries, damages, and losses, including, but not limited to: medical and related expenses, loss of income and support,

and diminished economic horizons. Plaintiff has also suffered and will continue to suffer other losses and damages, including, but not limited to: diminished capacity for the enjoyment of life, a diminished quality of life and grief.

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
NEGLIGENCE

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

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

122. 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.

123. 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.

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

125. 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.

126. 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.

127. 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.

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

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

130. 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.

131. 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 the severity of INVOKANA's effect on renal function;

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.

132. 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.

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

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

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

136. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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

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

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

139. 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.

140. 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.

141. 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 severe kidney damage, diabetic ketoacidosis, stroke, heart attack and amputation.

142. 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.

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

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

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

146. 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.

147. 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.

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

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

150. 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.

151. 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.

152. 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.

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

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

155. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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
FRAUDULENT MISREPRESENTATION

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

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

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

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

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

158. 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.

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

160. 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.

161. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

162. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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
NEGLIGENT MISREPRESENTATION

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

164. 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.

165. 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.

166. 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.

167. 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.

168. 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.

169. 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 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, adverse side effects.

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

171. 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.

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

173. 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.

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

175. 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.

176. 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.

177. 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.

178. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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 X
FRAUDULENT CONCEALMENT

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

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

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

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

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

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

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

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

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

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

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

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

186. The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA.

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

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

189. Defendants, by concealment or other action, intentionally prevented Plaintiff and his health care professionals from acquiring material information regarding the lack of safety

of INVOKANA, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

190. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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 XI
FRAUD

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

192. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, his prescribing health care professionals, the health care industry, and consumers that INVOKANA had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

193. 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.

194. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase INVOKANA, despite the risk of severe life-threatening injury, which Defendants knew were caused by the products.

195. 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 subject product's risks.

196. 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.

197. 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 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 severe kidney damage and sequelae, and would require monitoring while treating with INVOKANA drug therapy; and/or

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

198. Defendants had access to material facts concerning the defective nature of the subject 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.

199. 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.

200. 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.

201. 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.

202. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to use and in fact used INVOKANA, thereby sustaining injuries and damages.

203. Defendants knew and had reason to know that Plaintiff and his health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and his health care professionals would not have prescribed and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

204. 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 harm of severe kidney damage.

205. 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.

206. 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.

207. 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.

208. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of his right big toe and other related health complications. 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
PUNITIVE DAMAGES ALLEGATIONS

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

210. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved

an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard of the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and his healthcare providers.

211. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

212. Plaintiff therefore asserts claims for exemplary damages.

213. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

214. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of INVOKANA. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of INVOKANA, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting INVOKANA, despite their knowledge and awareness of these serious side effects and risks.

215. Defendants had knowledge of and were in possession of evidence demonstrating that INVOKANA caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of INVOKANA.

216. Although Defendants knew or recklessly disregarded the fact that INVOKANA causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute INVOKANA to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

217. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing INVOKANA and consumers from purchasing and ingesting INVOKANA, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming INVOKANA.

218. Defendants knew of INVOKANA's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by INVOKANA.

219. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate 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 out of Defendants.

220. Prior to the manufacture, sale, and distribution of INVOKANA, Defendants knew that the drug was in a defective condition 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 drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of INVOKANA to risk of injury or death.

221. Despite their knowledge, Defendants, acting through their 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 adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. 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.

222. Defendants' conduct was committed 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.

PRAYER FOR RELIEF

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

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;
5. Punitive damages;
6. Prejudgment interest at the highest lawful rate allowed by law;
7. Interest on the judgment at the highest legal rate from the date of judgment until collected;
8. Attorneys' fees, expenses, and costs of this action; and
9. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff demands an individual trial by jury on all issues which may be tried by a jury.

Dated this 1st day of October 2018.

Respectfully Submitted,

/s/ Edward A. Wallace
Edward A. Wallace
Lauren C. Kaplan
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Attorneys for Plaintiff

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Robin Boren

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

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Edward A. Wallace and Lauren C. Kaplan, Wexler Wallace LLP, 55 W Monroe Street, Suite 3300, Chicago, IL 60603, eaw@wexlerwallace.com, lck@wexlerwallace.com, 312-346-2222

DEFENDANTS

Janssen Pharmaceuticals, Inc. et al.

County of Residence of First Listed Defendant Mercer County, NJ
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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)***:
N.J.S.A. 2A:58C-1, et seq

Brief description of cause:
Personal injuries relating to the use of Invokana

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 10/01/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Edward A. Wallace

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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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.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Robin Boren

Plaintiff

v.

Janssen Pharmaceuticals Inc. et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson
One Johnson & Johnson Plaza,
New Brunswick, New Jersey 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Edward A. Wallace
Lauren C. Kaplan
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, IL 60603

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Robin Boren

Plaintiff

v.

Janssen Pharmaceuticals Inc. et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Ortho, LLC
c/o S.M. Rosenberg
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Edward A. Wallace
Lauren C. Kaplan
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, IL 60603

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Robin Boren

Plaintiff

v.

Janssen Pharmaceuticals Inc. et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Edward A. Wallace
Lauren C. Kaplan
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, IL 60603

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Robin Boren

Plaintiff

v.

Janssen Pharmaceuticals Inc. et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research and Development, LLC
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Edward A. Wallace
Lauren C. Kaplan
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, IL 60603

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset