UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	MDL No. 2750 Master Docket No. 3:16-md-2750
Warren Prout, Sr., Plaintiff, vs. Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC, Defendants.	JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4 CIVIL ACTION NO.:_____

COMPLAINT

Plaintiff Warren Prout, Sr. 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 Louisiana, as the place of remand as this case may have originally been filed there.

Plaintiff by and through the undersigned attorney, submits this Complaint and jury demand against Defendants JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, JANSSEN ORTHO, LLC, and JANSSEN PHARMACEUTICALS, INC.

As more specifically set forth below, Plaintiff maintains that the diabetes drug, Invokana, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warning to the dangers associated with its use. This case is being filed in accordance with Case Management Order No. 4 of the *In re: Invokana* MDL No. 2750.

NATURE OF ACTION

1. Defendants are the manufacturers of the prescription drug Invokana, developed and indicated for the treatment of type 2 diabetes. It was initially approved by the FDA in January of 2014 and is in a class of new diabetes drugs called glucose cotransporter-2 ("SGLT2") inhibitors. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. As the name suggests, SGLT-2 inhibitors decrease sugar in the bloodstream by inhibiting glucose reabsorption. The extra sugar is then eliminated from the body through urine produced by the user's kidneys, putting extra strain on the kidneys of patients that already have increased insult to their kidneys by virtue of having diabetes.

2. In May 2015, the FDA issued a safety communication warning that SGLT-2 inhibitors (including Invokana) can cause life-threatening diabetic ketoacidosis ("DKA"), having discovered more than 20 cases that had been reported to FDA's adverse event reporting system ("FAERS"). Although DKA in Type 1 diabetics occurs with some frequency, it is uncommon in Type 2 diabetics.

3. On May 16, 2017, the FDA issued a safety communication confirming that Invokana use increases the risk of leg and foot amputations, based on data from two large clinical trials. This led to the FDA requiring a black boxed warning to be added to the label of Invokana, Invokamet and Invokamet XR (the latter two being combination drugs of Invokana and metformin, another oral hypoglycemic) regarding the risk of amputation. The risk was not found to be associated with the entire class of SGLT-2 inhibitors, only with Invokana. Therefore, this safety communication and the black box warning was not for the entire class of SGLT-2 inhibitors, but was solely for Invokana, Invokamet and Invokamet XR. On June 12, 2017, results from a large study sponsored

by Defendants and examining safety outcomes with Canagliflozin (CANVAS) was published in the *New England Journal of Medicine* that showed an increased risk of amputations in users of Invokana.

4. The Plaintiff herein, Warren Prout, Sr., had type 2 diabetes, used Invokana and developed an infection that led to amputation of metatarsal bones and a portion of the left foot. Plaintiff contends that the Defendants knew of this risk with Invokana, but failed to inform him or his doctor regarding this risk, and therefore bring this Complaint against Defendants.

PARTIES

5. Plaintiff Warren Prout, Sr. ingested and was physically harmed by the Defendants' product.

6. At all relevant times since Warren Prout, Sr.'s initial use of Invokana, Plaintiff was and is a resident of Laplace, Louisiana, located in St. John the Baptist Parish.

7. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICIA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Janssen"), was at all relevant times, a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson and Johnson. At all times relevant and material hereto, Janssen was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Invokana, in New Jersey and Louisiana and throughout the United States.

8. Janssen is registered to do business throughout the United States, including New Jersey and Louisiana, where Plaintiff resides and where Plaintiff was treated for his injuries.

9. Janssen, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

10. Janssen is the wholly owned subsidiary of Johnson & Johnson ("J&J"). J&J and Janssen worked together to achieve the common business purpose of selling and profiting from Invokana.

11. Janssen's President and Chief Executive Officer at all relevant times reports directly to a J&J Company Group Chairman, who in turn reports to J&J's Executive Committee and Board of Directors. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

12. J&J and Janssen executives were also members of a Pharmaceutical Global Operating Committee, through which J&J set overall corporate goals that guided Janssen's strategic and tactical plans for Invokana. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

13. J&J established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, J&J supervised and controlled corporate sales goals; drug research; development, and manufacturing; medical affairs; regulatory affairs and compliance; legal affairs; and public relations. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

14. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, is a limited liability company organized under the laws of New Jersey which has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ. Defendant Janssen Research & Development, LLC (formerly known as Johnson & Johnson Pharmaceutical Research and Development, LLC,

and hereinafter referred to as "Janssen R&D"), is a New Jersey limited liability company. Janssen R&D is a wholly owned subsidiary of Centocor Research & Development, Inc., which is not a publicly held corporation. Centocor Research & Development, Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania, Janssen R&D is registered to do business throughout the United States, including in New Jersey and Louisiana, where Plaintiff reside and where plaintiff Warren Prout, Sr. was treated for his injuries.

15. Janssen R&D is registered to do business throughout the United States, including in New Jersey where the case is filed and in Louisiana where Plaintiff Warren Prout, Sr. resides and received treated for his injuries.

16. Janssen R&D, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, an/or development, and/or FDA approval, and/or marketing of Invokana.

17. Defendant JOHNSON & JOHNSON (hereinafter "J&J"), is a fictitious name adopted by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Invokana.

18. J&J, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

19. Defendant, JANSSEN ORTHO, LLC ("Ortho") is a Delaware limited liability company with a principal place of business at State road 933 Km 01, Street Statero, Gurabo, Puerto Rico 00778. Ortho is a wholly-owned subsidiary of Johnson & Johnson. At all times relevant

hereto, Defendant Ortho manufactures, and continues to manufacture Invokana. At all times relevant hereto, Defendant Ortho derived, and continues to derive, substantial revenue from goods and products developed, marketed, sold, distributed and disseminated and used in New Jersey, Louisiana, and throughout the United States.

20. Ortho, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

21. At all times alleged herein, Defendants shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

22. 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.

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

FACTUAL ALLEGATIONS

A. General Allegation

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

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

26. 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.

27. 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.

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

29. 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.

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

31. 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, Warren Prout, Sr.

32. 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.

33. 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.

34. 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.

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

36. 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.

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

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

39. 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.

40. 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.

41. 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.

42. 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.

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

44. 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.

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

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

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

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

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

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

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

56. 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.

57. 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 Warren Prout, Sr.

58. 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.

59. 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 rechallenge 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.

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

61. 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.

62. 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.

63. 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.

64. 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.

65. 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 Warren Prout, Sr. throughout the United States, including Louisiana and New Jersey.

66. 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.

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

68. 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.

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

70. Consumers, including Warren Prout, Sr., have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

B. Specific Allegations

71. Warren Prout, Sr. had several alternative and safer methods to treat his diabetes, including diet and exercise and other diabetes medications. Warren Prout, Sr. was prescribed Invokana on or about June 2014 and used it as directed.

72. In June 2014, Warren Prout, Sr. was prescribed Invokana to be taken once by mouth daily to improve glycemic control as an adjunct to diet and exercise.

73. In or about approximately October 2015 through October 2016, as a direct result of his treatment with Invokana, Warren Prout, Sr. developed several infections and diabetic ulcers on his left foot.

74. In or about October 2015 through October 2016, as a direct result of his treatment with Invokana, Warren Prout, Sr. began would care for treatment of the diabetic ulcers and infections.

75. In or about approximately October 2015 through October 2016, as direct result of his use of INVOKANA, Warren Prout, Sr. underwent several surgeries for amputations of the toes and metatarsal bones of the left foot.

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

77. Plaintiff now requires assistance from his spouse for many daily activities of living.

78. Warren Prout, Sr. 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.

79. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused Warren Prout, Sr.'s permanent injuries and damages.

80. Warren Prout, Sr.'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.

81. Defendants had a duty to warn Warren Prout, Sr.'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 Warren Prout, Sr. and his physicians known the risks associated with the use of SGLT2 inhibitors, including Invokana, Warren Prout, Sr. would not have been prescribed Invokana, would not have taken Invokana, and/or he would have been adequately monitored for its side effects, and as a result, would not have suffered injuries and damages from using Invokana.

82. Warren Prout, Sr.'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 Warren Prout, Sr.'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.

83. Warren Prout, Sr. 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 Warren Prout, Sr. 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.

84. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Warren Prout, Sr. made an independent decision to use Invokana in reference to the overall benefits and risks communicated by Defendants.

85. Warren Prout, Sr.'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.

FRAUDULENT CONCEALMENT

87. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

88. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of

diligence on his part.

89. Plaintiff or his physicians could not reasonably have discovered the injury and its cause before the date of the May 16, 2017 FDA safety communication.

90. Defendants were under a continuing duty to disclose the true character, quality and nature of Invokana and components identified herein, to the Plaintiff as well as his physicians. Because of their concealment of the true character, quality and nature of Invokana to Plaintiff, Defendants are estopped from relying on any statute of limitations defense.

91. As a result of Defendants' unlawful and fraudulent concealment of the effects of Invokana, the running statute of limitations has been suspended with respect to claims that Plaintiff could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before the Complaint was filed.

LIABILITY UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

92. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint with the same force and effect as if fully set forth herein.

93. Under the Louisiana Products Liability Act, Plaintiff shows that the serious risks associated with Invokana and other related injuries are the direct and proximate result of breaches of obligations owed by Defendants to Plaintiff, including defects in design, marketing, manufacturing, distribution, instructions and warnings by Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

a. Failure to instruct and/or warn of the serious risks of diabetic ketoacidosis, kidney failure and amputations, resulting in injuries;
b. Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who prescribed Invokana to Plaintiff, of the serious risks of

diabetic ketoacidosis, kidney failure and amputations, resulting in injuries;

c. Manufacturing, producing, promoting, creating, and/or designing Invokana without adequately testing it;

d. Failing to provide adequate warning of the dangers associated with Invokana;

e. The defects in designing, researching, developing, manufacturing, marketing, promoting and selling a pharmaceutical drug when it knew or reasonably should have known of the high risk of diabetic ketoacidosis, kidney failure and amputations;

f. Defendants' liability under the Louisiana Products Liability Act as a result of its design, development, manufacture, marketing, labeling and sale of a pharmaceutical drug which is defective and unreasonably dangerous;

g. The continued production and sale of the Invokana given the propensity of the pharmaceutical drug to cause diabetic ketoacidosis, kidney failure and amputations, resulting in subsequent surgery and injuries;

h. Providing inaccurate labeling and inadequate warnings and instructions with Invokana;

i. Other breaches and defects which may be shown through discovery or at trial; and

j. Generally, the failure of Defendants to act with the required degree of care commensurate with the existing situation.

94. At all times relevant, Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Invokana into the stream of commerce, including a duty to assure that Invokana did not pose a significantly increased risk of bodily harm to its users as well as a duty to comply with federal requirements. Defendants breached this duty.

95. Defendants owed a duty to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of Invokana, and otherwise distributing the pharmaceutical drug. Defendants breached this duty.

96. Defendants owed a duty of care to provide adequate warnings and instructions to the physicians, providers, suppliers, patients, distributors, or other end users of Invokana. Defendants breached this duty.

97. Defendants performed inadequate evaluation and testing on Invokana where such evaluation and testing would have revealed the propensity of Invokana to cause diabetic ketoacidosis, kidney failure, amputations, and other complications and injuries that Plaintiff has experienced.

98. Prior to and after the dates of Plaintiff being prescribed Invokana and the subsequent amputation of his left foot toes and metatarsal bones, the Defendants were on notice that Invokana caused serious complications, including diabetic ketoacidosis, kidney failure and amputations.

99. Defendants had a duty to perform post-marketing testing of Invokana; investigate the root cause of these complications; suspend sales and distribution; and warn physicians and patients of the propensity of Invkona cause diabetic ketoacidosis, kidney failure and amputations. Defendants breached this duty.

100. Plaintiff, as a purchaser of Invokana, is within the class of persons that the statutes, regulations and obligations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes, regulations and obligations are designed to prevent.

101. Defendants knew or should have known that the Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

102. As a direct and proximate result of Defendants' breach of the Louisiana Products Liability Act, Plaintiff suffered serious physical and mental injury, harm, damages, including but

not limited to past, present and future medical expenses and economic loss and will continue to suffer such harm, damages and economic loss in the future.

CLAIMS FOR RELIEF

COUNT ONE – STRICT PRODUCTS LIABILITY (Design Defect under LSA-RS 9:2800.56)

103. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

104. At all times herein mentioned, the pharmaceutical drug, Invokana, which was researched, designed, manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or distributed by Defendants, was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff Warren Prout, Sr.

105. Invokana was expected to and did reach the usual consumers, handlers, and persons, including Plaintiff, coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

106. At all times herein, the pharmaceutical drug, Invokana, which was researched, designed, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants, was in an unsafe, defective, and inherently dangerous condition when it left Defendants' possession and entered the stream of commerce. As designer, manufacturer, and/or seller of such pharmaceutical drugs, Defendants had a duty to design, manufacture, and sell pharmaceutical drugs that would not cause harm to users, including Plaintiff Warren Prout, Sr.

107. Invokana's unsafe, defective, and inherently dangerous condition was a cause of the injuries to the Plaintiff.

108. At all times herein mentioned, Invokana failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

109. Invokana is defective in design because of its propensity to cause diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations, and to cause patients unnecessary pain, surgical procedures and other complications.

110. Defendants were aware of the defects in design of Invokana.

111. Invokana is defective in design because the increased risk of developing diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations is unreasonably greater than other pharmaceutical drugs developed for treatment of type 2 diabetes.

112. Plaintiff Warren Prout, Sr. is and was a foreseeable user of Invokana, and he was prescribed Invokana is a manner reasonably foreseeable to Defendants.

113. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of Invokana. Further, in no way could Plaintiff have known that Defendants had designed, developed and manufactured Invokana in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

114. Invokana is and was being used in the Defendants' intended manner at the time it was prescribed to Plaintiff and during the time Plaintiff used Invokana.

115. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

116. Defendants knew or should have known that Invokana would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable product.

117. Defendants knew and foresaw or should have known or foreseen that patients who were prescribed Invokana, such as Plaintiff, could be and should have been affected by the defective design and composition of Invokana.

118. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

119. As a direct and proximate result of Defendants' placement of the defective pharmaceutical drug, Invokana, into the stream of commerce and Plaintiff's use of the defective drug as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future including all damages available under the Louisiana Products Liability Act.

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 herein contained be tried by a jury.

COUNT TWO – STRICT PRODUCTS LIABILITY
(Inadequate Warning Under LSA-RS 9:2800.57)

120. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

121. At all times material hereto, the Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced Invokana into the stream of commerce knowing the pharmaceutical drug would then be prescribed to patients being treated for type 2 diabetes. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including the

Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of Invokana. Defendants breached this duty.

122. Invokana was expected to, and did, reach the Plaintiff without substantial change or adjustment in its condition as designed, manufactured, and sold by the Defendants.

123. Invokana as designed, developed, tested, manufactured, marketed, labeled, sold, and/or placed in the stream of commerce by Defendants was in an unreasonably dangerous and defective condition when it left the hands of the Defendants and posed a threat to any user of the drug when put to its intended and reasonably anticipated use.

124. Plaintiff Warren Prout, Sr. was and is in the class of persons that Defendants actually considered, or should have considered, to be subject to the harm caused by the defective nature of Invokana.

125. Invokana, placed into the stream of commerce by Defendants, is defective due to inadequate warning because Defendants knew or should have known that Invokana caused these specific complications, therefore giving rise to physical injury, pain and suffering, debilitation, and the potential need for amputation, with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks.

126. The drug Invokana was prescribed to Plaintiff and used by Plaintiff in a manner reasonably anticipated by Defendants.

127. Defendants failed to timely and reasonably warn Plaintiff Warren Prout, Sr. and his physicians of material facts regarding the safety and efficacy of Invokana. Had they done so, proper warnings would have been heeded and no healthcare professional, including Plaintiff's physicians, would have prescribed Invokana, and no consumer, including Plaintiff, would have purchased and/or used Invokana.

128. Invokana, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate warnings and/or instructions because, after Defendants knew or should have known that there was reasonable evidence of an association between Invokana and the development of diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations, causing serious injury and pain, Defendants failed to provide adequate warnings to healthcare professionals and the consumer public, including Plaintiff and Plaintiff's physician, and continued to aggressively promote Invokana.

129. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331 and 333, and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

130. Defendants failed to provide adequate and timely warnings regarding Invokana and its known defects, including but not limiting to the propensity for diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

131. In addition, Defendants acquired knowledge of characteristics of Invokana that may cause damage and the danger of such characteristics, or the Defendants would have acquired such knowledge had the Defendants acted as a reasonably prudent manufacturer. Accordingly, Defendants are liable for the damages caused by their subsequent failure to use reasonable care to provide an adequate warning regarding such characteristics and their dangers to users and handlers of Invokana.

132. As a direct and proximate result of Defendants' placement of the defective drug Invokana into the stream of commerce and Plaintiff's use of the defective drug Invokana as

designed, manufactured, labeled, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff Warren Prout, Sr. suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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 herein contained be tried by a jury.

COUNT THREE – NEGLIGENCE

133. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

134. At all times relevant times, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Invokana.

135. 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 to cause or increase the harm of diabetic ketoacidosis, kidney failure, sepsis, and the life threatening complications of those conditions in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

136. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling Invokana.

137. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of Invokana to diabetic ketoacidosis, kidney failure, sepsis, and the life threatening complications of those conditions, in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

138. Defendants had a duty to accurately communicate the risks and benefits of Invokana to physicians, healthcare providers, and patients.

139. As a result of the Defendants' aggressive marketing campaigns promoting off-label uses, including for type 1 diabetes, weight loss, and to improve blood pressure and kidney function, Defendants knew or should have known and expected that consumers would use Invokana for such off-label uses.

140. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including diabetic ketoacidosis, kidney failure and sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee; these injuries were foreseeable.

141. Warren Prout, Sr. and his physicians did not know the nature and extent of the injuries that could result from Invokana and were misinformed about the benefits of Invokana and could not have discovered this information independently.

142. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling Invokana, and failing to adequately test and warn of the risks and dangers of Invokana.

143. Despite the fact that Defendants knew or should have known that Invokana caused unreasonable, dangerous side effects, Defendants continued to market Invokana to consumers, including Warren Prout, Sr., when there were safer alternative methods available.

144. Defendants' negligence was a foreseeable and proximate cause of Warren Prout, Sr.'s injuries, harm and economic loss which he suffered, as described and prayed for herein.

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 herein contained be tried by a jury.

COUNT FOUR - BREACH OF IMPLIED WARRANTY

145. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

146. Defendants impliedly warranted to Warren Prout, Sr. and his physicians and health care providers that Invokana was of merchantable quality and safe and fit for the use which it was intended.

147. The product did not conform to representations made by the manufacturer.

148. Warren Prout, Sr. reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants when using Invokana.

149. As a result, Warren Prout, Sr. used the Defendants' product as it was warranted and intended.

150. Invokana was not of merchantable quality, as warranted by Defendants because it was dangerous when used as intended and can cause severe injuries to consumers.

151. As a result of Defendants' breach of implied warranties, Plaintiff suffered permanent injuries and 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 herein contained be tried by a jury.

COUNT FIVE - BREACH OF EXPRESS WARRANTY
(Breach of Express Warranty Under LSA-RS 9:2800.58)

152. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

153. Defendants made and continue to make representations to consumers, including Plaintiff Warren Prout, Sr. and/or his physicians, regarding the character or quality of Invokana, including, but not limited to, statements that Invokana is a safe and effective drug for treatment of type 2 diabetes.

154. Defendants expressly warranted to Plaintiff's physicians and Plaintiff by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians and the public that Invokana is safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

155. The "Warnings and Precautions" section of the Invokana prescribing information purports to expressly describe the relevant and material side-effects that Defendants knew or should have known about.

156. In particular, the Consumer Medication Guide did not include any language that would suggest Invokana has been associated with diabetic ketoacidosis, kidney failure, blood infections, kidney infections, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

157. Invokana was defective in that when it left the Defendants' hands, it did not conform to Defendants' representations.

158. Plaintiff and/or Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Invokana.

159. As a direct and proximate result of Defendants' placement of the defective drug Invokana into the stream of commerce and Plaintiff Warren Prout, Sr.'s use of the defective drug as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff Warren Prout, Sr. suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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 herein contained be tried by a jury.

COUNT SIX – STRICT PRODUCTS LIABILITY
(Construction/Composition Defect under LSA-RS 9:2800.55)

160. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

161. At all times material hereto, Defendants were the manufacturers, designers, researchers, distributors, sellers, and/or suppliers of Invokana and placed a product on the market

with a condition which rendered it unreasonably dangerous due to its propensity to cause diabetic ketoacidosis, kidney failure, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations. The subject product was unreasonably dangerous in construction or composition.

162. Invokana, which was prescribed to Plaintiff Warren Prout, Sr., was defective in its construction and/or composition when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could cause diabetic ketoacidosis, kidney failure, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations, therefore giving rise to physical injury, pain and suffering, debilitation, and the potential need for additional surgeries, with the attendant risks of complications and death from such further surgery.

163. As a direct and proximate result of the defective manufacture or construction of Invokana and Plaintiff's use of the defective drug as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants and/or the Defendants' failure to comply with federal requirements, Plaintiff Warren Prout, Sr. suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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 herein contained be tried by a jury.

COUNT SEVEN – BREACH OF WARRANTY IN REDHIBITION

164. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

165. The drug Invokana contains a vice or defect which renders it useless or its use so inconvenient that consumers, including Plaintiff, would not have purchased it had they known about the vice or defect.

166. Pursuant to Louisiana Civil Code Article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. Invokana, which was sold and promoted by Defendants, possess a redhibitory defect because it is unreasonably dangerous, as described above, which renders Invokana useless or so inconvenient that it must be presumed that Plaintiff would not have bought Invokana had he known of the defects.

167. Defendants were aware of the substantial risks associated with Invokana but failed to fully disclose those risks to Plaintiff Warren Prout, Sr.

168. In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of Invokana, are deemed to be aware of its redhibitory defects.

169. Had Plaintiff been made aware of the defects contained in Invokana, he would not have purchased the drug. The risks associated with Invokana are characteristics that renders it unfit for its intended purpose.

170. Defendants are liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff a product unfit for its intended use.

171. Plaintiff is entitled to the return of purchase price paid for Invokana, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees and costs, pecuniary and non-pecuniary damages, as well as any other damages from his injuries and legal and equitable relief to which Plaintiff may be entitled.

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 herein contained be tried by a jury.

COUNT EIGHT - FRAUDULENT MISREPRESENTATION

172. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

173. Defendants intentionally and fraudulently misrepresented the safety and efficacy of Invokana in the product label.

174. Specifically, Defendants intentionally and fraudulently:

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

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

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

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

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

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

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

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

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

j. Affirmatively asserted that Invokana was safe and effective.

175. 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 Warren Prout, Sr., other consumers, Warren Prout, Sr.'s physicians, and the medical community.

176. The representations were made by the Defendants with the intent that doctors and patients, including Warren Prout, Sr. and his physicians, rely upon them.

177. Defendants' representations were made with the intent of defrauding and deceiving Warren Prout, Sr., other consumers, Warren Prout, Sr.'s physicians, and the medical community to induce and encourage the sale of Invokana.

178. Defendants J&J, Janssen, and Janssen R&D, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug Invokana was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, sepsis, or foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee. Warren Prout, Sr., his doctors, and others relied upon these representations.

179. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations Warren Prout, Sr. suffered amputation of the toes and metatarsal bones of his left foot. Plaintiff has incurred medical and related expenses. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

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 herein contained be tried by a jury.

COUNT NINE – UNJUST ENRICHMENT

180. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

181. Plaintiff conferred a benefit on Defendants by purchasing Invokana.

182. Plaintiff, however, did not receive a safe and effective drug for which Plaintiff paid.

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

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

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 herein contained be tried by a jury.

PUNITIVE DAMAGES ALLEGATIONS

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

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

187. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Invokana and failed to warn the public, including Plaintiff, of the extreme risk of permanent injury occasioned by said defects inherent in Invokana. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Invokana knowing these actions would

expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits. Said conduct was motivated by the reprehensible motive of increasing monetary profits for the sale of Invokana.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages as well as exemplary damages and loss of wages to which he is entitled by law, as well as all costs of this action, to the full extent of the law including:

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

DEMAND FOR A TRIAL BY JURY

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

[SIGNATURE BLOCK ON NEXT PAGE]

RESPECTFULLY SUBMITTED,

IRPINO, AVIN & HAWKINS LAW FIRM

/s/ Anthony D. Irpino
Anthony D. Irpino (#24727)
Louise C. Higgins (#31780)
Kacie F. Gray (#36476)
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kgray@irpinolaw.com

Attorneys for Plaintiff

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: May 14, 2018

RESPECTFULLY SUBMITTED,

IRPINO, AVIN & HAWKINS LAW FIRM

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Attorneys for Plaintiff

JS 44 (Rev. 06/17)

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

Warren Prout Sr

(b) County of Residence of First Listed Plaintiff St. John the Baptist Parish,
(EXCEPT IN U.S. PLAINTIFF CASES)

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

Anthony Irpino, Louise Higgins & Kacie Gray - Irpino, Avin & Hawkins Law Firm; 2216 Magazine St. New Orleans, LA 70130; 504-525-1500

DEFENDANTS

Janssen Pharmaceuticals Inc f/k/a Janssen Pharmaceuticia Inc., f/k/a Ortho-McNeil-Janssen Pharmeuticals, Inc., et al.

County of Residence of First Listed Defendant Mercier 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)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Healthcare Personal Injury/ Product Liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Brian Martinotti DOCKET NUMBER 2750

DATE 05/14/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Anthony D. Irpino

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

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

Warren Prout Sr.

Plaintiff

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant

Civil Action No. 2018-cv-9217

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:

Anthony D. Irpino
Louise C. Higgins
Kacie F. Gray
2216 Magazine Street
New Orleans, LA 70130

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. 2018-cv-9217

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:

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

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Warren Prout Sr.

Plaintiff

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant

Civil Action No. 2018-cv-9217

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:

Anthony D. Irpino
Louise C. Higgins
Kacie F. Gray
2216 Magazine Street
New Orleans, LA 70130

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. 2018-cv-9217

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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:

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

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Warren Prout Sr.

Plaintiff

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant

Civil Action No. 2018-cv-9217

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Janssen Pharmeuticals, 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:

Anthony D. Irpino
Louise C. Higgins
Kacie F. Gray
2216 Magazine Street
New Orleans, LA 70130

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. 2018-cv-9217

PROOF OF SERVICE

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

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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):*

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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:

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

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Warren Prout Sr.

Plaintiff

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant

Civil Action No. 2018-cv-9217

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research & 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:

Anthony D. Irpino
Louise C. Higgins
Kacie F. Gray
2216 Magazine Street
New Orleans, LA 70130

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. 2018-cv-9217

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❒ 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):*

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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

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Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: