

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN)
PRODUCTS LIABILITY LITIGATION

ERWING OLIVARES, ON BEHALF OF
JOSEFA SARMIENTO, DECEASED

Plaintiffs,

vs.

JANSSEN PHARMACEUTICALS, INC.;
JANSSEN RESEARCH & DEVELOPMENT,
LLC; JOHNSON & JOHNSON; and
JANSSEN ORTHO, LLC c/o S.M. Rosenberg,

Defendants.

MDL No. 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. _____

JURY DEMANDED

DIRECT FILED COMPLAINT PURSUANT TO CMO NO. 4

Plaintiff files this Complaint pursuant to CMO No. 4, and is bound by the rights, protections, 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, Erwing Olivares, on behalf of Josefa Sarmiento, Deceased, brings this case against Defendants for injuries suffered as a direct result of Decedent's ingestion of the pharmaceutical product INVOKANA. Plaintiff alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff's Decedent 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, Inc., Janssen Research & Development, LLC, Johnson & Johnson, and Janssen Ortho, LLC, concealed, and continued to conceal, their knowledge of INVOKANA’s unreasonably dangerous risks from Plaintiff, 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’s decedent, suffered severe and permanent personal injuries, including amputation.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants’ actions and inactions, Josefa Sarmiento developed severe infection resulting in the amputation of her right leg above the knee. Ms. Sarmiento’s ingestion of the defective and unreasonably dangerous drug INVOKANA caused injury and damage.

PARTIES

5. Josefa Sarmiento was at all relevant times, a resident and citizen of Kenner, Jefferson Parish, Louisiana, and was prescribed, purchased, ingested and exposed to *canagliflozin* (INVOKANA[®]), which was developed, manufactured, promoted, marketed, distributed, and sold by Defendants. Ms. Sarmiento suffered damages as a result of Defendants’ illegal and wrongful conduct alleged herein. Ms. Sarmiento began taking INVOKANA some time in 2015.

6. Defendant, Janssen Pharmaceuticals, Inc. (“Janssen”) was at all 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 & Johnson. At all times relevant and material hereto, Janssen was, and still is, a pharmaceutical company involved in

manufacturing, research development, marketing, distribution, sales, and release for use to the general public of pharmaceuticals, including INVOKANA, in Louisiana and throughout the United States.

7. Janssen is registered to do business throughout the United States, with ties and business dealings that occurred within the State of Louisiana where Plaintiff resided and was treated.

8. 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.

9. Janssen is a wholly owned subsidiary of Johnson & Johnson. Janssen and Johnson & Johnson worked together to achieve the common business purpose of selling INVOKANA.

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

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

12. Johnson & Johnson established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, Johnson & Johnson supervised and controlled corporate sales goals; during research;

development and manufacturing; medical affairs; regulatory affairs and compliance; legal affairs; and public relations. At all relevant times, Johnson & Johnson and Janssen worked together to achieve the common purpose of selling INVOKANA.

13. Defendant, Janssen Research & Development, LLC (“Janssen R&D”), 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 08560. Defendant 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, is registered to do business throughout the United States, with ties and business dealings that occurred within the State of Louisiana, where Plaintiff resided and was treated.

14. Janssen R&D, 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.

15. Defendant Johnson & Johnson (“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 J&J was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling INVOKANA.

16. 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.

17. 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 00788. Ortho is a wholly owned subsidiary of J&J. 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 throughout the United States, with ties and business dealings that occurred within the State of Louisiana, where Plaintiff resided and was treated.

18. 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.

19. At all times alleged herein, Defendants shall include all named or unnamed parent companies, parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and any organization 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

20. 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.

21. Venue in this action properly lies in this jurisdiction pursuant to 28 U.S.C. § 1391(a) because, at all times material hereto, Defendants had their principal place of business in this district and (b) Defendants conducted substantial business in this district. Additionally, the Multi-District Litigation was created and assigned to this District.

FACTUAL ALLEGATIONS

A. General Allegations

22. This action is brought for damages on behalf of Plaintiff Josefa Sarmiento. Plaintiff was prescribed and supplied with, received, and took the prescription drug INVOKANA. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering the severe and life-threatening side effect of amputation caused by INVOKANA.

23. INVOKANA is a member of a gliflozin class of pharmaceuticals also known as sodium glucose co-transporter 2 (“SGLT2”) inhibitors.

24. SGLT2 inhibitors, including INVOKANA, inhibit renal glucose reabsorption through the SGLT2 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.

25. SGLT2 inhibitors, including INVOKANA, are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose co-transporter receptors, including SGLT1.

26. SGLT1 and SGLT2 receptors are located throughout the body, including the kidneys, intestines, and brain.

27. INVOKANA has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States.

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

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

30. 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.

31. Indeed, Defendants published advertisements on their company website and issued press releases announcing favorable information about INVOKANA. For example, the FDA's approval of INVOKANA on March 29, 2013 was announced on the J&J website. On March 14, 2016, J&JU issued a press release announcing, "First Real-Work Evidence Comparing an SGLT2 inhibitor with DPP-4 Inhibitors show Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA[®] (canagliflozin)." The former announcements did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

32. Through these advertisements, press releases, publications, and websites, J&J has purposefully directed activities nationally including towards residents of the State of Louisiana.

33. The INVOKANA-related pages on Defendants' websites are accessible from within the State of Louisiana and have been indexed by search engines so that they are located through searches that are conducted from within the State of Louisiana.

34. Defendant J&J also published information touting the strong sales of INVOKANA in its corporate reports and in earning calls

35. Further, J&J employees had responsibility for overseeing promotion strategies for the drug INVOKANA.

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

37. Defendant J&J has the ability and the duty to improve the labeling of INVOKANA to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, etc.

38. 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.

39. J&J employees hold the 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.

40. In fact, J&J so substantially dominates and controls the operation 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.

41. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing right to INVOKANA in North American, and marketed, advertised, distributed, and sold INVOKANA in the United States, with ties and business dealings that occurred within the State of Louisiana where Plaintiff resided and was treated.

42. In May 2012, Janssen R&D submitted an NDA to the FDA for approval to market INVOKANA in the United States.

43. In March 2013, the FDA approved INVOKANA as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

44. As part of its marketing approval of INVOKANA, the FDA required the Defendants to conduct five post-marketing studies: 1) a cardiovascular outcomes trial; 2) an enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; 3) a bone safety study; 4) and 5) two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamics study and safety efficacy study.

45. 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.

46. 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 cardiovascular outcomes.

47. Defendants' marketing campaign willfully and intentionally misrepresented the risks of INVOKANA and failed to warn about the risk of severe diabetic ketoacidosis, acute kidney injury, amputation, and other injuries.

48. INVOKANA is one of the Defendants' top selling drugs with annual sales exceeding \$1 billion.

49. In September 2015, the FDA announced that INVOKANA causes premature bone loss and fractures.

50. In December 2015, the FDA announced that INVOKANA causes diabetic ketoacidosis, pyelonephritis (kidney infections), and urosepsis.

51. In March 2016, the FDA announced that INVOKANA causes severe renal impairment, angioedema, and anaphylaxis.

52. In May 2016, the FDA announced that INVOKANA has been linked to an increased risk of amputations.

53. At all times 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 injuries suffered by Plaintiff herein

54. 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 life threatening complications, including, but not limited to, severe diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, and amputation and its sequelae.

55. Specifically, Defendants knew or should have known of the risks of severe diabetic ketoacidosis, kidney failure, and amputation 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. INVOKANA selectivity for the SGLT1 receptor;
- b. Animal studies demonstrating increased ketones when given INVOKANA;
- c. Studies of SGLT1 inhibitor phlorizin, and its propensity to cause ketoacidosis;

- d. Reports involving people with familial glycosuria, indicating a propensity to develop ketoacidosis;
- e. Clinical studies demonstrating increases in glucagon in people taking INVOKANA;
- f. Clinical studies, adverse event reports, and case report demonstrating increased ketones in people taking INVOKANA;
- g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and volume depletion in people taking INVOKANA;
- h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking INVOKANA;
- i. Clinical studies, adverse event reports, and case reports demonstrating re-challenge responses in increasing ketones and diabetic ketoacidosis in people taking INVOKANA; and
- j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking INVOKANA compared to other glucose-lowering medications.

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

57. 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.

58. Defendants were aware that the mechanism of action for INVOKANA places extraordinary strain on patients' kidneys.

59. Despite their knowledge of data indicating that INVOKANA use is causally related to the development of severe diabetic ketoacidosis, kidney failure, and amputation, Defendants promoted and marketed INVOKANA as safe and effective for persons, such as Plaintiff named herein, throughout the United States, including the State of Louisiana.

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

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

62. Despite Defendants' knowledge of the increased risk of 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.

63. 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 severe diabetic ketoacidosis, acute kidney injury, amputation, cardiovascular problems, and the life-threatening complications thereof.

64. Consumers, including Plaintiff named herein, have several alternative safer methods for treating diabetes, including diet and exercise and other anti-diabetic agents.

B. Specific Allegations

65. Plaintiff's Decedent, Josefa Sarmiento, had several alternative and safer methods to treat her diabetes, including diet and exercise and other diabetes medications. Ms. Sarmiento was prescribed INVOKANA some time in 2015 by her doctor and used it as directed.

66. After approximately 16 months of use and as a direct result of Ms. Sarmiento's treatment with INVOKANA, she was admitted to Ochsner Medical Center in March of 2017 to have her right leg amputated above the knee.

67. Plaintiff endured pain and suffering, 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.

68. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

69. Plaintiff'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 risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA. Their conduct and the product defects were substantial factors in bringing about the Plaintiff's injuries.

70. Defendants had a duty to warn Plaintiff's prescribing physician about the risks of INVOKANA use, including the risks of diabetic ketoacidosis, kidney failure, amputation, and resulting complications.

71. Had the Plaintiff's physician known the risks associated with the use of SGLT2 inhibitors, including INVOKANA, Plaintiff would not have been prescribed INVOKANA and would not have taken INVOKANA, and/or Plaintiff would have been adequately monitored for its side effects and as a result, would not have suffered injuries and damages from using INVOKANA.

72. Plaintiff'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 Plaintiff'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.

73. Plaintiff 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 Plaintiff directly, through print and television advertising, and indirectly, through the Plaintiff's healthcare providers and others who have been exposed to Defendants' claims through their comprehensive marketing campaigns.

74. Based on the Defendants' direct-to-consumer advertising and Defendants' misrepresentations and omissions, Plaintiff made an independent decision to use INVOKANA based on the overall benefits and risks communicated by Defendants.

75. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's hazards, and were not reasonable foreseeable to Plaintiff or Plaintiff's physicians.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS

BREACH OF EXPRESS WARRANTY

76. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, with the same force and effect as if more fully set out herein.

77. At all times hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing

INVOKANA, which is unreasonably dangerous and defective, thereby placing INVOKANA into the stream of commerce.

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

- a. Was safe and fit for its intended purpose;
- b. Was of merchantable quality;
- c. Did not produce any dangerous side effects, and
- d. Had been adequately tested and found to be safe and effective for the treatment of diabetes.

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

80. Defendants advertised, labeled, marketed, and promoted INVOKANA, representing the quality to healthcare professionals, Plaintiff, and the public in such a way as to induce INVOKANA's purchase or use, thereby making an express warranty that INVOKANA would conform to the representations. More specifically, the prescribing information for INVOKANA did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

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

Plaintiff and her health care professionals, including the “Warnings and Precautions” section, purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurately nor adequately set forth.

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

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

84. Neither Plaintiff nor Plaintiff’s prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants’ statements and representations concerning INVOKANA.

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

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

87. As a foreseeable, direct, and proximate consequence of Defendants’ actions, omissions, and misrepresentations, Plaintiff suffered severe amputation of her right leg above the knee. In addition, Plaintiff required healthcare and related services. Plaintiff incurred medical and

related expenses. Plaintiff also suffered 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 incurred mental and physical pain and suffering.

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS

STRICT LIABILITY – DEFECTIVE DESIGN

88. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. At all relevant times Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed INVOKANA, including the INVOKANA used by Plaintiff, as described above.

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

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

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

- a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe to be used as intended, subjecting Plaintiff risks that exceeded the benefits of the drug;
- b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making use of the drug more dangerous than an ordinary customer would expect and more dangerous than other risks associated with the treatment of diabetes;
- c. INVOKANA was insufficiently tested;
- d. INVOKANA caused harmful side effects that outweighed any potential utility;
- e. Defendants were aware at the time INVOKANA was marketed that ingestion of INVOKANA would result in an increased risk of heart attack and other injuries;
- f. Inadequate post-marketing surveillance; and/or
- g. There were safer alternative designs and formulations that were not utilized.

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

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

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

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

97. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and

otherwise endure that INVOKANA was not reasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

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

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

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

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

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

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

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

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

105. Due to the unreasonably dangerous condition of INVOKANA, Defendants are liable to Plaintiff.

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

107. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of her right leg above the knee, and other related health complications. In addition, Plaintiff required healthcare and services, for which she incurred medical and related expenses. Plaintiff suffered 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 included physician care, monitoring, and treatment. Plaintiff incurred mental and physical pain and suffering. For all of these injuries and damages, Erwing Olivares brings this suit on behalf of Josefa Sarmiento, now deceased.

THIRD CAUSE OF ACTION
AGAINST THE DEFENDANTS

STRICT LIABILITY – FAILURE TO WARN

108. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

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

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

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

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

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

116. Defendants negligently and recklessly labeled, distributed, and promoted INVOKANA.

117. Defendants had a continuing duty to warn Plaintiff of the dangers associated with INVOKANA.

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

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

120. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that INVOKANA caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks

associated with its use. The dangerous propensities of INVOKA, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

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

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

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

- a. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risks of injuries with the use of INVOKANA;
- b. Continued to aggressively promote INVOKANA even after Defendants knew or should have know of the unreasonable risks from use;
- c. Failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

- d. Failed to provide warnings, instructions, or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with INVOKANA's capacity to cause its users to suffer diabetic ketoacidosis, kidney damage, and/or amputation;
- e. Failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and
- f. Overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotions, the risks associated with the use of INVOKANA.

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

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

126. Had the Defendants properly disclosed and disseminated the risks associated with INVOKANA, Plaintiff would have avoided the risk of developing injuries as alleged herein.

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

128. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of her right leg above the knee, as well as other related health complications. In addition, Plaintiff required healthcare and services. Plaintiff incurred medical and related expenses. Plaintiff suffered 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 incurred mental and physical pain and suffering.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS

STRICT LIABILITY – MANUFACTURING DEFECT

129. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

130. 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.

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

132. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketing, 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 particulars:

- a. When placed in the stream of commerce, INVOKANA contained manufacturing defects which rendered the 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/or
- d. The subject product's manufacturing defects existed before it left the control of Defendants.

133. As a direct and proximate result of the design defect and Defendants misconduct set forth herein, Plaintiff suffered serious and permanent physical and emotional injuries,

expended large sums of money for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally, and economically injured.

DAMAGES

As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of her right leg above the knee, and other related health complications. In addition, Plaintiff required healthcare and medical services, for which she incurred related expenses. Plaintiff's quality of life was greatly diminished. Plaintiff's direct medical losses and costs included physician care, monitoring, and treatment. Plaintiff incurred mental and physical pain and suffering. For all these injuries and damages, Erwing Olivares brings this suit on behalf of Josefa Sarmiento, now deceased.

PRAYER FOR RELIEF

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

1. Judgment for Plaintiff and against Defendants;
2. Awarding compensatory damages to Plaintiff for past damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs and medical monitoring, together with interest and costs as provided by law;
3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
4. Awarding Plaintiff's reasonable attorneys' fees;

5. Awarding Plaintiff the costs of these proceedings; and
6. Such other and further relief as this Court deems just and proper.

Respectfully submitted by:

/s/ Esther Berezofsky

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ATTORNEYS FOR PLAINTIFFS

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

ERWING OLIVARES, ON BEHALF OF JOSEFA SARMIENTO, DECEASED

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Esther Berezofsky, Berezofsky Law Group, LLC, 210 Lake Drive East, Suite 101, Cherry Hill, NJ 08002 Telephone - 856 667 0500

DEFENDANTS

JANSSEN PHARMACEUTICALS, INC., ET AL

County of Residence of First Listed Defendant STATE OF NEW JERSEY (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

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

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location (Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation).

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

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. Sec. 1332. Brief description of cause: Product Liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 11/30/2018 SIGNATURE OF ATTORNEY OF RECORD /s/ Esther Berezofsky

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 statute.
- 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.