UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION Sherry Cox and Rick Cox, Plaintiffs, vs. Janssen Pharmaceuticals Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC c/o S.M. Rosenberg and Mitsubishi Tanabe Pharma Development America Inc., Defendants.	MDL 2750 Master Docket No. 3:16-md-2750 JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN **DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO.4** Civil Action No.:_____

AMENDED COMPLAINT

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

Plaintiffs, Sherry Cox and Rick Cox, by and through undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

I. PARTIES

1. At all relevant times of Sherry Cox's initial use of Invokana, Sherry Cox (hereafter Plaintiff) and Rick Cox (collectively Plaintiffs) were and are residents of Homestead, Florida located in Miami-Dade County.

2. 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 Florida and throughout the United States.

3. Janssen is registered to do business throughout the United States, including Florida and states where Plaintiff has resided and was treated.

4. 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.

5. Janssen is the wholly owned subsidiary of J&J. J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

6. 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.

7. 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.

8. 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.

9. 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 publically 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 Florida, where Plaintiff resided and was treated.

10. Janssen R&D is registered to do business throughout the United States, including Florida, where Plaintiff has resided and was treated.

11. 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.

12. 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.

13. 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.

14. 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 Florida and throughout the United States.

15. 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.

16. Defendant, MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC., (hereinafter "Tanabe") is involved in the licensing agreements for pharmaceuticals and drug therapies including Invokana. Defendant Tanabe is a subsidiary of Mitsubishi Tanabe Pharma Corporation. Tanabe is headquartered at 525 Washington Boulevard, Suite 400, Jersey City, NJ 07310. Tanabe has transacted and conducted business within the State of Florida. Tanabe licenses pharmaceuticals and drug therapies including Invokana for its parent corporation Mitsubishi Tanabe Pharma Corporation.

17. Tanabe, 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.

18. 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.

II. JURISDICTION AND VENUE

19. 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.

20. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(b) because, at all times material hereto, Plaintiffs resided and were citizens of Homestead, Florida in Miami-Dade County.

III. FACTUAL ALLEGATIONS

A. GENERAL ALLEGATIONS

21. This action seeks, among other relief, general and special damages and equitable relief due to Sherry Cox suffering severe and life threatening side effects of diabetic ketoacidosis caused by Invokana including acute kidney injury.

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

23. 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.

24. 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.

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

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

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

28. 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, Sherry Cox.

29. Defendant Tanabe, in collaboration with the other defendants, designed and developed the diabetes drug, Invokana.

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 websites 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 web site. On April 1, 2013, Tanabe announced the approval of 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 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 web sites, J&J has purposefully directed activities nationally including towards residents of Florida.

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

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

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

36. 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.

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

41. 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 Florida and the remainder of the United States.

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: 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.

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 adverse cardiovascular outcomes.

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

48. Invokana is one of 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 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 Sherry Cox 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 diabetic ketoacidosis and its sequelae and kidney failure and its sequelae.

55. 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. 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, indication a propensity to develop ketoacidosis;

e. Clinical studies demonstrating increases in glucagon in people taking Invokana;

f. Clinical studies, adverse even reports, and case reports demonstrating increased ketones in people taking Invokana;

g. Clinical studies, adverse even 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 even reports and case reports demonstrating re challenge responses in increasing Ketones and diabetic ketoacidosis in people taking Invokana;

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 the kidneys and renal system.

59. Despite its knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis and kidney failure, Defendants promoted and marketed Invokana as safe and effective for persons such as Sherry Cox throughout the United States, including Florida.

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 minimize 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 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.

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

64. Consumers, including Sherry Cox, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

B. SPECIFIC ALLEGATIONS

65. Sherry Cox had several alternative and safer methods to treat her diabetes, including diet and exercise and other diabetes medication. Sherry Cox was prescribed Invokana in or around November, 2014 by her doctor and used it as directed.

66. Sherry Cox was prescribed Invokana to be taken once by mouth daily to improve glycemic control as an adjunct to diet and exercise.

67. After less than one (1) year of use and as a direct result of her treatment with Invokana, Sherry Cox was admitted to Baptist Hospital of Miami in Miami, Florida on August 2, 2015 with symptoms of abdominal pain, nausea and vomiting.

68. Sherry Cox was ultimately diagnosed with diabetic ketoacidosis, and acute kidney injury.

69. Sherry Cox was discharged on August 8, 2015 with orders from the doctor to discontinue Invokana.

70. Sherry Cox 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.

71. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused Sherry Cox's injuries and damages.

72. Sherry Cox'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. The conduct and the product defects were substantial factor in bringing about Plaintiffs' injuries.

73. Defendants had a duty to warn Sherry Cox's prescribing physicians about the risks of Invokana use, including the risk of diabetic ketoacidosis and resulting complications.

74. Had Sherry Cox and her physicians known the risks associated with the use of SGLT2 inhibitors, including Invokana, Sherry Cox would not have been prescribed Invokana, would not have taken Invokana, and/or she would have been adequately monitored for its side effects and as a result, would not have suffered injuries and damages from using Invokana.

75. Sherry Cox'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 Sherry Cox'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.

76. Sherry Cox 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 Sherry Cox directly, through print and television advertising, and indirectly, through his healthcare providers and others who have been exposed to Defendant's claims through its comprehensive marketing campaigns.

77. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Sherry Cox made an independent decision to use Invokana based on the overall benefits and risks communicated by Defendants.

78. Sherry Cox'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.

IV. CLAIMS FOR RELIEF

COUNT ONE – STRICT PRODUCTS LIABILITY - FAILURE TO WARN

79. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

80. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Sherry Cox. The design

defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

81. Invokana's inadequate warnings rendered Invokana unreasonably dangerous and defective.

82. Defendants' defective warnings for Invokana were reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants made conscious decisions not to adequately warn about risks they know or should have known about. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Invokana.

83. Sherry Cox was prescribed and used Invokana for its intended purposes and for purposes that the defendants expected and could foresee.

84. Defendants expected and intended Invokana to reach, and did in fact reach, Sherry Cox without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

85. Sherry Cox could not have discovered the unwarned risks of using Invokana through the exercise of reasonable care.

86. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Invokana were incomplete and inadequate.

87. Sherry Cox did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Sherry Cox or to

her treating physicians. The warnings that were given by the Defendants were not accurate and were incomplete.

88. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take other such steps as necessary to ensure that Invokana did not cause users to suffer from unreasonable and dangerous risks.

89. 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.

90. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug and failure to warn Sherry Cox and her physicians about the significant risks inherent in Invokana therapy, Sherry Cox suffered the injuries and damages alleged herein.

COUNT TWO – STRICT PRODUCTS LIABILITY - DESIGN DEFECT

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

92. Defendants had a duty to properly design, manufacture, compound, test, inspect, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such

steps as to assure that Invokana did not cause users to suffer from unreasonable and dangerous side effects.

93. The aforesaid product was defective and unsafe in design and manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Sherry Cox.

94. Invokana was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Invokana failed to warn of the dangerous risks posed by Invokana, including the risk of developing diabetic ketoacidosis and kidney damage.

95. Invokana was defective and Defendants knew that Invokana was to be used by consumers without inspection for defects. Moreover, Sherry Cox's prescribing physicians and other health care providers neither knew nor had reason to know at the time of Sherry Cox's use of Invokana of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

96. Invokana was prescribed to and used by Sherry Cox as intended by Defendants and in a manner reasonably foreseeable to Defendants.

97. The design of Invokana was defective in that the risks associated with using Invokana outweighed any benefits of the design. Any benefits associated with the use of Invokana were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

98. The defect in design existed when the product left Defendants' possession.

99. At the time Invokana left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Invokana.

100. As a result of Invokana's defective condition, Sherry Cox suffered the injuries and damages alleged herein.

COUNT THREE – NEGLIGENCE

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

102. 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.

103. 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, and the life threatening complications of those conditions.

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

105. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of Invokana to diabetic ketoacidosis, kidney failure, and the life threatening complications of those conditions.

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

107. 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.

108. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including diabetic ketoacidosis and kidney failure, and these injuries were foreseeable.

109. Sherry Cox 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.

110. 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.

111. 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 Sherry Cox, when there were safer alternative methods available.

112. Defendants' negligence was a foreseeable and proximate cause of the Sherry Cox's injuries, harm, economic loss and damages she suffered as alleged herein.

COUNT FOUR – BREACH OF IMPLIED WARRANTY

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

114. Defendants impliedly warranted to Sherry Cox and Sherry Cox's physicians and health care providers that Invokana was of merchantable quality and safe and fit for the use which it was intended.

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

116. Sherry Cox reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants when using Invokana.

117. As a result, Sherry Cox used the Defendants' product as it was warranted and intended.

118. 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.

119. As a result of Defendants' breach of implied warranties, Plaintiff suffered the injuries and damages alleged herein.

COUNT FIVE – BREACH OF EXPRESS WARRANTY

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

121. 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.

122. 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.

123. 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, or kidney infections.

124. Sherry Cox's physician prescribed Invokana and Sherry Cox consumed Invokana reasonably relying on these warranties. Sherry Cox's physician and Plaintiff could not have learned independently that Defendants were false and misleading.

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

126. Defendants knew or should have known Sherry Cox would rely on their warranties.

127. Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of the Defendants.

128. The warranties and representations are false. Invokana can cause diabetic ketoacidosis, kidney failure, blood infections, and kidney infections.

129. Invokana does not conform to the Defendants' express representations; therefore, Defendants have breached the express warranties.

130. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Sherry Cox's injuries and damages as alleged herein.

COUNT SIX – FRAUDULENT MISREPRESENTATION

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

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

133. 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 inforamation about the safe and effective use of INVOKANA" and fraudulently omits information Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events;

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

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

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

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

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

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

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

j. Affirmatively asserted that Invokana was safe and effective.

134. 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 Sherry Cox, other consumers, Sherry Cox's physicians, and the medical community.

135. The representations were made by the Defendants with the intent that doctors and patients, including Sherry Cox and her physicians, rely upon them.

136. Defendants' representations were made with the intent of defrauding and deceiving Sherry Cox, other consumers, Sherry Cox's physicians, and the medical community to induce and encourage the sale of Invokana.

137. 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, etc. Sherry Cox, her doctors, and others relied upon these representations.

138. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Sherry Cox suffered diabetic ketoacidosis and other related health complications. Plaintiff has incurred medical and related expenses. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering as well as the injuries and damages alleged herein.

COUNT SEVEN –– NEGLIGENT MISREPRESENTATION

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

140. Defendants made misrepresentations to Sherry Cox's physicians, Sherry Cox, and the general public from the time Invokana was first tested until now. The misrepresentation includes but is not limited to the misrepresentation that Invokana is safe, fit, and effective for human consumption.

141. Defendants owed a duty to Sherry Cox to exercise reasonable care and ensure they did not misrepresent the safety or efficacy of Invokana.

142. Defendants failed to exercise that reasonable care and have therefore breached their duty to Sherry Cox.

143. Defendants had a duty to correct these material misstatements because they knew or should have known the statements were false and others would reasonable rely on them and suffer injury.

144. These misrepresentations were made directly by the defendants, by agents of the Defendants, and in written material directed to physicians, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of the subject product.

145. The representations by the defendants were in fact false, in that Invokana is not safe, fit, and effective for human consumption, using Invokana is hazardous to health, and Invokana has a serious propensity to cause serious injuries to users, including but not limited to the injuries and damages suffered by Plaintiff Sherry Cox as alleged herein .

COUNT EIGHT – UNJUST ENRICHMENT

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

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

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

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

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

COUNT NINE – LOSS OF CONSORTIUM

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

152. At all relevant times Rick Cox was and is the spouse of Plaintiff Sherry Cox.

153. As a result of the injuries sustained by Plaintiff Sherry Cox, as set forth above, Rick Cox has suffered loss of consortium, including but not limited to, mental anguish and the loss of his wife's support, service, society, companionship, comfort, affection, love and solace.

154. As a result of the injuries sustained by Plaintiff, as set forth above, Plaintiffs sustained damage to their marital relationship.

V. PUNITIVE DAMAGES ALLEGATIONS

155. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Sherry Cox 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.

156. 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 Sherry Cox and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Invokana.

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

158. 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 Sherry Cox, entitling Plaintiff to exemplary damages.

VI. PRAYER FOR RELIEF

159. Wherefore, Plaintiffs demands judgment against Defendants for compensatory damages as well as exemplary damages and loss of wages to which they are entitled by law, as well as all costs of this action, to the full extent of the law including:

1. Judgment for Plaintiffs and against Defendants;
2. Damages to compensate Plaintiff for injuries and economic losses suffered as a result of the use of Invokana, including 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, trebled on all applicable counts;
5. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;
6. A trial by jury on all issues of the case; and,
7. For any other relief as this court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied including but not limited to reasonable attorneys' fees and costs and expert fees.

DEMAND FOR A TRIAL BY JURY

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

Respectfully Submitted,

Dated: March 17, 2017

/s/ Frank Petosa
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