UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION _____ THIS DOCUMENT RELATES TO: Mark R. Goldring, Individually, and Ilene Goldring, Spouse Plaintiff vs. Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Johnson & Johnson Company, and Janssen Ortho, LLC, Defendants	Master File No. 3:16-md-2750 MDL No. 2750 JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGMENET ORDER NO. 4 Civil Action No.: 3:17-cv-11519

COMPLAINT

COMES NOW Plaintiffs, Mark R. Goldring ("Ingesting Planintff") and Ilene Golddring, who file this Complaint pursuant to Case Management Order ("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, Plaintiffs hereby designate the United States District Court for the District of New Jersey as the place of remand as this case may have originally been filed there. Plaintiffs file this Complaint for causes of action against Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho, LLC and Johnson & Johnson Company, (Collectively referred to as "Defendants") and allege as follows upon information and belief:

I. INTRODUCTION

1. This is an action for personal injury, statutory, compensatory, and punitive damages due to Plaintiffs as a result of Defendants' concealment of risks associated

with their drug Invokana® ("Invokana"), their defective design of Invokana, and Defendants' over promotion of the drug for non-approved, or "off-label", indications.

II. JURISDICTION

2. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy between Plaintiffs and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of being incorporated in and having their headquarters and principal place of business within this judicial district.

III. PARTIES

3. Plaintiffs, Mark R. Goldring and Ilene Goldring, at all relevant times, were residents of the State of New Jersey and used Invokana for the treatment of type 2 diabetes, and for other purposes marketed by Defendants.

4. Defendant Janssen Pharmaceutical, Inc., f/k/a Janssen Pharmaceutica, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter referred to as "JPI") is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson Company.

5. JPI is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. At all relevant times, Defendant JPI regularly and continuously transacted and conducted business in all States of the United States within this judicial district including labeling, packaging, marketing, advertising, distributing

and selling Invokana. At all relevant times, JPI was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Invokana for use as an oral prescription medication.

6. JPI is a wholly owned subsidiary of Defendant Johnson & Johnson Company.

7. Defendant Janssen Research & Development, LLC f/k/a Johnson & Johnson Research & Development, LLC (hereinafter referred to as "R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

8. Defendant R&D is also a subsidiary of Defendant Johnson & Johnson Company.

9. As part of its business, R&D is involved in the design, development, research, manufacture, testing, marketing, distribution, and sale of pharmaceutical products, including Invokana. At all relevant times, Defendant R&D regularly and continuously transacted and conducted business in all States of the United States within this judicial district including labeling, packaging, marketing, advertising, distributing and selling Invokana.

10. At all relevant times, R&D was in the business of, and did design, develop, research, test, market, distribute and sell the drug Invokana for use as an oral prescription medication.

11. Defendant Janssen Ortho, LLC (hereinafter referred to as " Ortho") is a limited liability company organized under the laws of Delaware, having its principal place of business at State Road 933 Km 0.1, Street Statero, Gurabo, Puerto Rico 00778.

12. Defendant Ortho is also a subsidiary of Defendant Johnson & Johnson Company.

13. As part of its business, Ortho is involved in the design, development, research, testing, manufacture, marketing, distribution and sale of pharmaceutical products, including Invokana. At all relevant times, Defendant Ortho regularly and continuously transacted and conducted business in all States of the United States within this judicial district including labeling, packaging, marketing, advertising, distributing and selling Invokana.

14. At all relevant times, Ortho was in the business of and did design, develop, research, manufacture, test, advertise, promote, market, sell and distribute the drug Invokana for use as an oral prescription medication.

15. Defendant Johnson & Johnson Company (hereinafter referred to as " J&J") is a fictitious name adopted by Defendant Johnson & Johnson Company, a New Jersey corporation with its principle place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

16. As part of its business, J&J and its "family of companies," including each and every other Defendant named herein, is involved in the design, development, research, marketing, distribution and sale of pharmaceutical products, including Invokana. At all relevant times, Defendant J&J regularly and continuously transacted and conducted business in all States of the United States including Louisiana and Wyoming and within this judicial district including labeling, packaging, marketing, advertising, distributing and selling Invokana.

17. At all times herein mentioned, each Defendant was the agent, servant, partner, predecessor in interest, and joint venture of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

IV. FACTUAL BACKGROUND

18. In March 2013, the United States Food and Drug Administration (FDA) approved Defendants' compound *Canigliflozin*, marketed by defendants as Invokana, for the treatment of type 2 diabetes.

19. Invokana is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 (SGLT2) inhibitors.

20. Defendant, J&J, in collaboration with its Japanese partner, initiated the initial design and development of Invokana.

21. Defendant, J&J, identifies in its 2010 annual report that "Canagliflozin is developed in collaboration with Mitsubishi-Tanabe Pharma Corporation."

22. Defendant, J&J, paid over $53,000 in fees, reimbursements, and honoria to a consultant for work the consultant performed in regards to Invokana's clinical trials.

23. Defendant, JPI, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including in the State of New Jersey, and Plaintiffs' home state, in collaboration with its parent, subsidiaries, and partners, including each and every Defendant named herein.

24. Defendant, R&D, in collaboration with Defendant, JPI, conducted clinical research, and testing which Defendants submitted to the FDA in support of Invokana's approval.

25. Defendant Ortho is known to manufacture Invokana in collaboration with its partners, including each and every Defendant named herein.

26. In designing, developing, researching, testing, manufacturing, distributing, and selling Invokana, each and every Defendant named herein acted in concert, or as each other's

agents, in furtherance of their joint enterprise, acting with the common goal to develop, manufacture, and sell Invokana to consumers, including Plaintiffs.

27. Each and every Defendant, either directly, or through their agents, designed, developed, researched, tested, manufactured, marketed, distributed or sold Invokana.

28. With 2015 sales of $1.3 billion, Invokana is one of Defendants' blockbuster drugs, even though it has only been on the market a few years.

29. Invokana's 2015 sales figures represent a 123% increase from the previous year's sales.

30. Invokana's tremendous sales figures are due to Defendants substantial marketing efforts directed to consumers and the medical community.

31. Since Invokana has been available to U.S. consumers, Defendants have spent nearly $27 million on Invokana related payments to doctors and hospitals.

32. Invokana is indicated only for treating type 2 diabetes.

33. Though Invokana is indicated only for this limited use, Defendants intentionally mislead consumers into believing that Invokana is indicated for weight loss, and has cardiovascular benefits.

34. Invokana is designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, an estimated 60% of glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk of kidney disease; resulting in increased stress on Invokana users' kidneys.

35. Because Invokana prevents a person from using a significant amount of the body's primary fuel, glucose, Invokana users must turn to an alternate fuel source, fat. As the

body begins to breakdown fat for fuel, acids called ketones are introduced into the blood stream, creating the potential for acidosis (increased acidity in the blood).

36. Because Defendants designed Invokana to lower blood-glucose in this way, Invokana users are at an increased and unreasonable risk of developing ketoacidosis, and severe kidney injuries, including renal failure.

37. Generally, when a person is suffering from ketoacidosis (excess ketones), they also report high blood-glucose levels, and frequent urination.

38. Normally, the body excretes excess ketones through urination in order to obtain proper blood-acid balance; however, because Invokana already places the kidneys under duress by forcing significant quantities of unmetabolized glucose through the urinary tract as everyday treatment for managing type 2 diabetes, Invokana users often are unable to obtain blood-acid balance through the normal process, urination, and frequently require medical intervention to prevent the acidosis from becoming life threatening.

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

40. Thus, Invokana's mechanism to treat high blood-glucose, expelling unmetabolized glucose through the urinary tract, which causes more frequent urination, is a process the body usually reserves for elevated glucose or acidosis emergencies.

41. Invokana forces this emergency process on its users in the normal course of treatment-every day.

42. Generally, ketoacidosis is rare for type 2 diabetics, but much more common in type 1 diabetics. Type 1 diabetics are at a greater risk of suffering ketoacidosis because,

like Invokana users, their bodies are unable to metabolize glucose for fuel, leaving a significant quantity to be expelled through the kidneys and out the urinary tract, forcing the body to tum to fat for fuel.

43. Ketoacidosis can lead to organ failure, including renal failure if not treated quickly.

44. Unfortunately for Invokana users, because the drug mimics a naturally occurring emergency process while lowering blood-glucose, key symptoms of ketoacidosis such as elevated blood-glucose and frequent urination are either not present or unrecognizable. Thus, Invokana users are often unaware they are suffering ketoacidosis until more severe injuries develop.

45. Since Invokana's introduction to U.S. consumers, the FDA has received a significant number of reports of diabetic ketoacidosis, and kidney injuries, including renal failure and kidney infection, among users of Invokana.

46. On May 15, 2015, the FDA issued a Public Health Advisory linking SGLT2 inhibitors, including Invokana, to diabetic ketoacidosis.

47. Recently, on December 4, 2015, it was the FDA that updated Invokana's warning label to warn of too much acid in the blood (ketoacidosis), and serious urinary tract infections, which can develop into full blown kidney infections.

48. Then, on June 14, 2016, the FDA required Defendants to strengthen the Invokana warning label by including the risk of acute kidney injury.

49. An analysis of the FDA adverse event database shows that patients taking Invokana are several times more likely to report diabetic ketoacidosis, and acute kidney injury, including renal failure, than those taking other diabetes drugs to treat high blood-glucose.

50. Defendants' clinical trials and other data available to Defendants before they sold Invokana to Plaintiffs indicated that Invokana causes renal failure, or increases the risk of the occurrence of renal failure.

51. Given the state of the scientific field, Defendants intentional design of Invokana, and the data generated through Defendants' phase I-IV clinical trials, post marketing trials, and reported adverse events, Defendants' knew or should have known before they sold Invokana to Plaintiffs that Invokana was likely to cause Plaintiffs' harm as complained of herein.

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

53. Defendants' failure to warn about diabetic ketoacidosis is particularly detrimental to those taking the drug because in many cases of Invokana induced ketoacidosis, the signs of ketoacidosis are masked by the effects of the drug.

54. Moreover, unrecognized acidosis can lead to severe, and permanent kidney damage, including renal failure.

55. Consumers, including Plaintiffs, who have used Invokana for treatment of diabetes, have several alternative safer products available to treat the conditions, such as Metformin, Onglyza, Januvia and Jardiance.

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

57. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of Invokana and willfully deceived Plaintiffs, their health care professionals, the medical community, and the general public as to the benefits, health risks and consequences of the use of Invokana.

58. As a direct result, on or about November 2, 2015, Defendants sold Invokana to Ingesting Plaintiff, and Ingesting Plaintiff began taking it to treat type 2 diabetes, and for other reasons marketed by Defendants.

59. Ingesting Plaintiff ingested and used Invokana as prescribed and in a foreseeable manner.

60. The Invokana used by Ingesting Plaintiff was provided to him in a condition substantially the same as the condition in which it was manufactured and sold by Defendants.

61. Ingesting Plaintiff agreed to initiate treatment with Invokana in an effort to reduce his blood-glucose, and because he was misled by Defendants into believing Invokana possesses indications or benefits which it does not.

62. Instead of being safe and effective as Invokana's alternatives are Invokana can cause severe injuries, such as those suffered by Ingesting Plaintiff, including Diabetic Ketoacidosis and Invokana has not been approved nor deemed safe and effective for either weight loss or reducing blood pressure, as Defendants represent.

63. After beginning Invokana treatment, and as a direct and proximate result thereof, Ingesting Plaintiff was diagnosed with Diabetic Ketoacidosis on or about October 1, 2016, requiring hospitalization and continued treatment.

64. Prior to ingesting Invokana, Ingesting Plaintiff exhibited no indication that he was at risk of renal failure.

65. Because Defendants concealed the true risks of Invokana from Plaintiffs and Plaintiffs' physicians, at the time Plaintiffs were injured, Plaintiffs had no way of knowing that Invokana was the cause, and that Defendants' conduct in the design, development, researching, testing, manufacturing, advertising, distribution and sale subjects them to liability for Plaintiffs' injuries.

66. Defendants knew or should have known the risks associated with the use of Invokana, including the risk of developing severe kidney injuries, including renal failure diabetic ketoacidosis.

67. The development of Plaintiffs' injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. This conduct, as well as the product defects complained of herein, were substantial factors in bringing about and exacerbating Plaintiff's injuries.

68. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects.

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

70. Ingesting Plaintiff would not have used Invokana had Defendants properly disclosed the risks associated with the drug, or had not overstated Invokana's benefits. Thus,

had Defendants properly disclosed the risks and benefits associated with Invokana, Ingesting Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting Invokana.

71. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and their physicians the true and significant risks associated with taking Invokana.

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

73. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of Invokana, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiffs seek actual, compensatory, and punitive damages from Defendants.

V. CLAIMS FOR RELIEF

COUNT I
(STRICT LIABILITY)

74. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense

possible, pursuant to all laws that may apply pursuant to choice of law principles, including the laws of this Court, and the Plaintiffs' resident State.

75. At the time of Plaintiffs' injuries, Defendants' pharmaceutical drug Invokana was defective and unreasonably dangerous to foreseeable consumers, including Plaintiffs.

76. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Invokana as hereinabove described that was used by the Ingesting Plaintiff.

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

78. At those times, Invokana was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiffs herein.

79. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Invokana.

80. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or suppliers,

it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

81. At all times herein mentioned, Invokana was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

82. Defendants knew, or should have known that at all times herein mentioned, their Invokana was in a defective condition, and was and is inherently dangerous and unsafe.

83. At the time of the Ingesting Plaintiff's use of Invokana, Invokana was being used for the purposes and in a manner normally intended, namely for the treatment of diabetes.

84. Defendants, with this knowledge, voluntarily designed their Invokana in a dangerous condition for use by the public, and in particular the Plaintiffs.

85. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

86. Defendants created a product unreasonably dangerous for its normal, intended use.

87. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Invokana left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

88. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Invokana was manufactured.

89. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiffs in particular; and Defendants are therefore strictly liable for the injuries sustained by Plaintiffs.

90. Plaintiffs could not, by the exercise of reasonable care, have discovered Invokana's defects herein mentioned and perceived its danger.

91. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening ketoacidosis, kidney injury, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

92. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

93. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening ketoacidosis, kidney injury, as well as other severe and permanent health consequences from Invokana, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Invokana.

94. The Invokana ingested by Ingesting Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

95. Ingesting Plaintiff did not misuse or materially alter their Invokana.

96. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. Invokana as designed, manufactured, sold and supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell Invokana;

c. Defendants failed to warn and place adequate warnings and instructions on Invokana;

d. Defendants failed to adequately test Invokana;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Invokana, and,

f. A feasible alternative design existed that was capable of preventing Plaintiffs' injuries.

97. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Invokana.

98. Defendants' defective design, manufacturing defect, and inadequate warnings of Invokana were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

99. That said defects in Defendants' drug Invokana were a substantial factor in causing' Plaintiffs' injuries.

100. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects including but not limited to, life-threatening ketoacidosis, kidney injury, as well as other severe and personal injuries which are permanent and lasting

in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

101. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT II
(MANUFACTURING DEFECT)

102. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

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

104. When it left the control of Defendants, Invokana was expected to, and did reach Plaintiffs without substantial change from the condition in which it left Defendants' control.

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

106. Specifically, Invokana was more likely to cause serious bleeding that may be irreversible, permanently disabling, and life-threatening than other anticoagulants.

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

108. Ingesting Plaintiff and his healthcare providers did not misuse or materially alter their Invokana.

109. As a direct and proximate result of the use of Invokana, Plaintiffs suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

COUNT III
(DEFECTIVE DESIGN)

110. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

111. 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 reaches consumers, such as Plaintiffs, who ingested it.

112. The design, development, testing, and research of Invokana occurred at Defendants JPI, R&D, and J&J's principle place of business, respectively, in the State of New Jersey, and various other facilities which Defendants maintain.

113. Invokana was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiffs.

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

115. Invokana was defectively designed m an unsafe, and inherently dangers condition because it intentionally forced its users to process significant quantities of unmetabolized glucose through the kidneys, creating the unreasonable risk of suffering ketoacidosis, and renal failure.

116. Invokana contains defects in its design which render the drug dangerous to consumers, such as Plaintiffs, when used as intended or as reasonably foreseeable to Defendants. The design defects render Invokana more dangerous than other diabetes medications and cause an unreasonable increased risk of injury, including but not limited to renal failure, renal impairment, renal insufficiency and ketoacidosis.

117. Invokana was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that Invokana was defective and unsafe, even when used as instructed.

118. The nature and magnitude of the risk of harm associated with the design of Invokana, including the risk of renal failure, renal impairment, renal insufficiency and ketoacidosis, is high in light of the intended and reasonably foreseeable use of Invokana.

119. The risks of harm associated with the design of Invokana are higher than necessary.

120. It is highly unlikely that Invokana users would be aware of the risks associated with Invokana through either warnings, general knowledge or otherwise, and Plaintiffs specifically were not aware of these risks, nor would they expecct them.

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

122. Invokana's design is more dangerous than a reasonably prudent consumer would expect when in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiffs expected.

123. The intended or actual utility of Invokana is not of such benefit or to justify the risk of renal failure, renal impairment, renal insufficiency and ketoacidosis.

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

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

126. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

127. The unreasonably dangerous nature of Invokana caused serious harm to Plaintiffs.

128. Ingesting Plaintiff's kidneys were injured, causing renal failure, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood-acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

129. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

130. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered personal and economic injuries. In addition, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT IV
(FAILURE TO WARN)

131. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect

as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

132. 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 reaches consumers, such as Ingesting Plaintiff, who ingested it.

133. The design, development, testing, researching, labeling and marketing of Invokana occurred at Defendants JPI, R&D, and J&J's principle place of business, respectively, in the State of New Jersey, and various other facilities which Defendants maintain.

134. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, 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, Plaintiffs, and other consumers, and therefore had a duty to warn of the risks associated with the use of Invokana.

135. Defendants expected Invokana to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

136. 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 serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

137. Invokana's prescribing information fails to adequately warn of the injuries complained of herein in that it:

a. provides no warning of injury to the kidney, such as renal failure;

b. downplays the risk of harm by indicating only patients with preexisting renal impairment are at risk of suffering a renal related adverse event;

c. does not warn that Invokana can cause permanent injury to the kidneys; and

d. downplays the risk of harm by including relevant information in the "Adverse Events" section rather than the "Warnings and Precautions" section.

138. Instead, prior to the FDA's mandated label change on June 16, 2016, Invokana's warning label merely notes that Invokana may impair renal function specifically stating "Impairment in Renal Function: Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL/minl .73 m^2 (2.2)."

139. Instead of warning of kidney injuries, Defendants go on to note in the "Adverse Reactions" section, not the "Warnings and Precautions" section, that Invokana was associated with renal-related adverse reactions "particularly in patients with moderate renal impairment."

140. Thus, in addition to failing to include any mention of kidney injuries in the warnings section, Defendants also mislead and downplay the risk of kidney injuries by

indicating only patients with preexisting renal impairment are at risk of suffering any kidney related adverse events.

141. Moreover, Renal function merely relates to the kidneys' ability to filter waste, and warning that the drug may impair renal function is not adequate to warn consumers and the medical community that the drug actually causes permanent harm to the kidneys, especially in light of Defendants attempt to downplay the risk of adverse events.

142. As described above, 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 Ingesting Plaintiff. Invokana contained warnings insufficient to alert consumers, including Plaintiffs, to the dangerous risks and reactions associated with Invokana, including the development of Plaintiffs' injuries.

143. At the time Defendants' sold Invokana to Plaintiffs, Defendants knew or should have known, based on their intentional design, pre-approval clinical trial data, post approval clinical trial data, and reported adverse events that Invokana can cause renal failure and that their warning was inadequate.

144. This defect caused serious injury to Plaintiffs, who used Invokana for its intended purpose and in a reasonably anticipated manner.

145. 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 unreasonable and dangerous risks.

146. Defendants negligently and recklessly labeled, distributed, and promoted Invokana because they knew or should have known of Invokana's defective nature, but failed to adequately warn consumers and the medical community.

147. Defendants had a continuing duty to warn Plaintiffs of the dangers associated with Invokana.

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

149. Plaintiffs could not have discovered any defects in Invokana through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

150. 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 Invokana, as referenced above, were known to Defendants, before they sold Invokana to Plaintiffs, through Defendants' pre-approval clinical trial data, post approval clinical trial data, and reported adverse events, 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.

151. Invokana, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiffs, in a reasonable and intended manner without knowledge of this risk of serious bodily harm.

152. 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.

153. 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 is 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 risk of injuries with use of Invokana;

b. continued to aggressively promote Invokana even after Defendants knew or should have known 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 the

severity of Invokana's effect on the kidneys;

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 promotion, the risks associated with the use of Invokana.

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

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

156. Had Defendants properly disclosed and disseminated the risks associated with Invokana, Plaintiffs would have avoided the risk of developing injuries as alleged herein by choosing a safer alternative product such as Metformin, Januvia, Onglyza or Jardiance.

157. The safer alternative diabetes prescription medications do not present the risk of injury as complained of herein, and they are otherwise safe and effective for the treatment of type 2 diabetes.

158. Instead, because of Defendants' false and misleading advertising, directed at consumers such as Plaintiffs, and the medical community, such as Plaintiffs' physicians, Ingesting Plaintiff began treatment with Invokana.

159. Plaintiff's kidneys were injured, causing renal failure, when Invokana's intended design forced significant amounts of unmetabolized glucose through Plaintiff's

kidneys, leading to a blood-acid imbalance, placing further stress on Plaintiff's kidneys as her body attempted to cope with the effects of excess acid, and Invokana.

160. Defendants are liable to Plaintiffs 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.

161. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

162. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries, ketoacidosis and other related health complications. In addition, Ingesting Plaintiff requires and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT V
(NEGLIGENCE)

163. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense

possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

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

165. The Defendants owed Plaintiffs and other consumers a duty to exercise reasonable care when designing, testing, manufacturing, marketing, advertising, distributing, and selling Invokana, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiffs and other consumers of the dangers associated with Invokana.

166. 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.

167. Defendants had a duty to disclose to health care professionals the causal relationship or association of Invokana to the development of Plaintiffs' injuries.

168. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of Invokana, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of Invokana, including the injuries suffered by Plaintiffs.

169. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold Invokana, Defendants knew, or in the exercise of reasonable care should have known, that their product was defective, dangerous, and otherwise harmful to Plaintiffs.

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

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

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

173. Defendants were further negligent in that they manufactured and produced a defective product, Invokana, knew and were aware of the defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the product's defects and risks.

174. The Defendants' failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test Invokana before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Invokana;

c. failing to conduct sufficient post-market testing and surveillance of Invokana;

d. designing, manufacturing, marketing, advertising, distributing, and selling Invokana to consumers, including Plaintiffs, without an adequate warning of the significant and dangerous risks of Invokana and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Invokana and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of Invokana's effect on the kidneys;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in its patients that do not already suffer from renal impairment;

h. failing to exercise due care when advertising and promoting Invokana; and

e. negligently continuing to manufacture, market, advertise, and distribute Invokana after the Defendants knew or should have known of its adverse effects.

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

176. Plaintiffs did not know the nature and extent of the injuries that could result from ingestion and use of Invokana.

177. But for Defendants' negligent conduct, Plaintiffs would have avoided harm by choosing a safer alternative treatment.

178. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiffs suffered, and will continue to suffer, as described herein because Invokana's intended design causes kidney failure.

179. Plaintiff's kidneys were injured, causing renal failure, when Invokana's intended design forced significant amounts of unmetabolized glucose through Plaintiff's kidneys, leading to a blood-acid imbalance, placing further stress on Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

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

Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

181. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries and other related health complications. In addition, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation

of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT VI
(BREACH OF EXPRESS WARRANTY)

182. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

183. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing Invokana, which is unreasonably dangerous and defective, thereby placing Invokana into the stream of commerce.

184. Defendants made express representations to Plaintiffs before and at the time of sale through various advertising, and prescribing material. For instance, Defendants prominently claim in their advertisements directed at the medical community and consumers, such as Plaintiffs, "Greater Reductions in body weight"; and "Greater Reductions in systolic blood pressure."

185. Additionally, Defendants prominently display a heart on their advertising directed at consumers, including Plaintiffs, representing that Invokana provides cardiovascular benefits even though the FDA has approved no such indication.

186. Further, Defendants expressly represented to Plaintiffs, other consumers, Plaintiffs' physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that Invokana:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. was approved, and deemed safe and effective for weight loss;

d. was approved, and deemed safe and effective for reducing blood pressure;

e. did not produce any dangerous side effects, and

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

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

188. Defendants advertised, labeled, marketed, and promoted Invokana, representing the quality to health care professionals, Plaintiffs, 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.

189. Despite this, Defendants expressly represented that Invokana was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat diabetes, safe and effective for weight loss, and safe and effective to reduce blood pressure. Portions of the prescribing information relied upon by Plaintiffs and his 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.

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

191. Invokana does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects which Defendants do not warn of, causes severe and permanent injuries, and because Invokana is not approved for weight loss or reducing blood pressure, as represented by Defendants. Therefore, Defendants breached the aforementioned warranties.

192. At all relevant times, Invokana did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

193. Neither Plaintiffs nor his prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning Invokana when Defendants sold Invokana to Ingesting Plaintiff.

194. Plaintiffs, other consumers, Ingesting Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting Invokana.

195. Had the prescribing information for Invokana accurately and adequately set forth the true risks associated with the use of such product, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiffs could have avoided the injuries complained of herein by seeking a safer alternative treatment.

196. After purchasing Invokana from Defendants and subsequently ingesting it, Ingesting Plaintiff's kidneys were injured, causing renal failure, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood-acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

197. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

198. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered severe kidney injuries, ketoacidosis and other related health complications. In addition, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death,

aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT VII
(BREACH OF IMPLIED WARRANTY)

199. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

200. Defendants manufactured, distributed, advertised, promoted, and sold Invokana.

201. At all relevant times, Defendants knew of the use for which Invokana was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

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

203. Invokana was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that Invokana has dangerous propensities when used as intended and can cause serious injuries, including kidney failure.

204. At all relevant times, Defendants intended that Invokana be used in the manner used by Plaintiffs, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that Invokana was not adequately tested.

205. Defendants were aware that consumers, including Plaintiffs, would use Invokana as marketed by Defendants. As such, Plaintiffs were a foreseeable user of Invokana.

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

207. Invokana was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiffs' injuries without adequately warning of said risks.

208. Plaintiffs and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell Invokana only if it was indeed of merchantable quality and safe and fit for its intended use.

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

210. Ingesting Plaintiff and his physicians reasonably relied upon Defendants' implied warranty for Invokana when prescribing and ingesting Invokana.

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

212. Invokana was expected to reach and did in fact reach consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

213. Defendants breached the warranties of merchantability and fitness for its particular purpose because Invokana was unduly dangerous as described above and caused undue injuries, including Plaintiffs' injuries.

214. The harm caused by Invokana far outweighed its alleged benefit, rendering Invokana more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

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

216. Defendants' breach of these implied warranties induced Ingesting Plaintiff to purchase Invokana from Defendants.

217. After purchasing and ingesting Invokana, Ingesting Plaintiff's kidneys were injured, causing renal failure, ketoacidosis, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood-acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

218. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

219. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries, ketoacidosis and other related health complications. In addition, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur

medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT VIII
(NEGLIGENT MISREPRESENTATION)

220. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

221. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning Invokana, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

222. Defendants disseminated to health care professionals and consumers through published labels marketing materials, and otherwise information that misrepresented the properties and effects of Invokana with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest Invokana.

223. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Invokana, knew or reasonably should have known that health care

professionals and consumers of Invokana rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting Invokana.

224. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Invokana were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

225. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of Invokana, knew or reasonably should have known that health care professionals would write prescriptions for Invokana in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for Invokana would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

226. From the time Invokana was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts, or misrepresented material facts, regarding the safety, indications, and efficacy of Invokana. Defendants made material misrepresentations to Plaintiffs, his health care professionals, the healthcare community, and the general public, including:

a. stating that Invokana had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-

threatening risks of harm to users of Invokana, when compared to comparable or superior alternative drug therapies;

c. misrepresenting that Invokana was approved and deemed safe and effective for weight loss;

d. misrepresenting that Invokana was approved and deemed safe and effective for reducing blood pressure; and

e. misrepresenting Invokana's risk of unreasonable, dangerous, adverse side effects.

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

228. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public, including Plaintiffs.

229. Defendants' misrepresentations were made before and at the time Defendants sold Invokana to Plaintiffs.

230. Defendants' misrepresentations were made through various means, including but not limited to advertising material which stated "Greater Reductions in body weight"; and "Greater Reductions in systolic blood pressure," and prescribing information which failed to adequately warn of the risks presented by Invokana.

231. Defendants made these representations in furtherance of their aggressive and misleading marketing campaign with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of Invokana

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

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

234. Defendants failed to exercise ordinary care in making their representations concerning Invokana and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of Invokana.

235. Defendants engaged in a nationwide marketing campaign, over-promoting Invokana in written marketing literature, in written product packaging, and in direct- to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Invokana while concealing, misrepresenting, and actively downplaying the serious, severe, and life- threatening risks of harm to users of Invokana, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented Invokana's risk of unreasonable and dangerous adverse side effects, as well as its benefits.

236. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Invokana, including Plaintiffs. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

237. But for Defendants' misrepresentations, Plaintiffs would have avoided harm by choosing a safer alternative treatment.

238. After purchasing and subsequently ingesting Invokana, Ingesting Plaintiff's kidneys were injured, causing renal failure, ketoacidosis, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood- acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

239. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

240. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries, ketoacidosis and other related health complications. In addition, Ingesting Plaintiff requires and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT IX
(FRAUDULENT MISREPRESENTATION)

241. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense

possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

242. Defendants made fraudulent misrepresentations with respect to Invokana in the following particulars:

a. defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Invokana had been tested and found to be safe and effective for the treatment of diabetes;

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

c. Defendants represented that Invokana had been approved and deemed safe and effective for weight loss; and

d. Defendants represented that Invokana had been approved and deemed safe and effective for reducing blood pressure.

243. 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 Plaintiffs, other consumers, Plaintiffs' physicians, and the medical community.

244. In furtherance of their aggressive and misleading marketing campaign, the representations were made by the Defendants with the intent that doctors and patients, including Ingesting Plaintiff and his physicians, rely upon them.

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

246. Ingesting Plaintiff, his doctors, and others reasonably relied upon these representations.

247. But for Defendants' misrepresentations, Ingesting Plaintiff would have not purchased Invokana.

248. After purchasing and subsequently ingesting Invokana, Ingesting Plaintiff's kidneys were injured, causing renal failure, ketoacidosis, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood- acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

249. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages in so as to punish Defendants and deter them from similar conduct in the future.

250. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries and other related health complications. In addition, Ingesting Plaintiff requires and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and

damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT X
(FRAUDULENT CONCEALMENT)

251. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the forgoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. The plaintiffs plead this cause of action in the broadest sense possible, pursuant to all laws that many apply pursuant to choice of law principles, including the law of the resident state(s) of the plaintiffs, regardless of whether arising under statute, common or civil law.

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

253. Defendants fraudulently concealed information with respect to Invokana in the following particulars:

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

b. Defendants represented that Invokana was safer than other alternative medications and fraudulently concealed information which demonstrated that

Invokana was not safer than alternatives available on the market; and

c. Defendants downplayed, and concealed the risk of kidney injury by emphasizing only those with preexisting renal impairment were at risk of suffering a renal related adverse event, and by including key information in only the "Adverse Events" section, rather than the "Warnings and Precautions" section.

254. Defendants were under a duty to Plaintiffs to disclose and warn of the defective and dangerous nature of Invokana because:

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

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

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of Invokana from Plaintiffs.

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

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

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

258. The concealment of information and the misrepresentations about Invokana were made by Defendants in furtherance of their aggressive and misleading marketing campaign with the intent that doctors and patients, including Plaintiffs, rely upon them so that Plaintiffs would request and purchase Invokana and his health care providers would prescribe and recommend Invokana.

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

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

261. After purchasing and subsequently ingesting Invokana, Ingesting Plaintiff's kidneys were injured, causing renal failure, ketoacidosis, when Invokana's intended design forced significant amounts of unmetabolized glucose through Ingesting Plaintiff's kidneys, leading to a blood- acid imbalance, placing further stress on Ingesting Plaintiff's kidneys as his body attempted to cope with the effects of excess acid, and Invokana.

262. Defendants, by concealment or other action, intentionally prevented Ingesting Plaintiff and his health care professionals from acquiring material information regarding the lack of safety of Invokana, thereby preventing Plaintiffs from discovering the truth. As such, Defendants are liable for fraudulent concealment.

263. Defendants' conduct as described above was committed with knowing conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

264. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ingesting Plaintiff suffered severe kidney injuries and other related health complications. In addition, Ingesting Plaintiff requires and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include physician care, monitoring, and treatment. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

COUNT XI
(VIOLATION OF CONSUMER PROTECTION LAWS/ CONSUMER FRAUD LAWS)

265. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

266. Ingesting Plaintiff used Invokana and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

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

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

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

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

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

269. Defendants violated consumer protection laws of various states.

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

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

272. As a result of these violations of consumer protection laws, Plaintiffs have incurred and will incur; serious physical injury (including in some cases death), pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital

and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

JURY TRIAL DEMANDED

Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;

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 the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Post judgment interest;

6. Awarding Plaintiffs reasonable attorneys' fees when applicable;

7. Awarding Plaintiffs the costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

Dated: November 10, 2017

Respectfully submitted,

By: /s/ *Douglas R. Plymale*
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Attorneys for Plaintiffs

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Mark R. Goldring and Ilene Goldring

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Douglas R. Plymale, Ph.D., The Dugan Law Firm, APLC; 365 Canal Street, Suite 1000, New Orleans, LA 70130; Telephone: (504) 648-0180

DEFENDANTS

Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Johnson & Johnson Company, and Janssen Ortho, LLC

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Brian Martinotti DOCKET NUMBER 2750

DATE
11/10/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Douglas R. Plymale, Ph.D.

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE