IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF KENTUCKY

LOUISVILLE DIVISION

ROSE ANN ADYE, Plaintiff, vs. JANSSEN RESEARCH & DEVELOPMENT L.L.C. f/k/a/ JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT L.L.C.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN ORTHO L.L.C.; MITSUBISHI TANABE PHARMA CORPORATION; AND JOHN DOES 1-50, Defendants.	Case No. 3:16-CV-107-JHM **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Rose Ann Adye, brings this case against Defendants for injuries suffered as a direct result of Plaintiff's ingestion of the pharmaceutical product Invokana®. Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and

because Defendants are incorporated and have their principal places of business in states other than the state in which the Plaintiff resides.

2. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of Kentucky, have committed a tort in whole or in part in the State of Kentucky, and have continuing contacts with the State of Kentucky.

PARTIES TO THIS COMPLAINT

3. At all times and relevant hereto, Plaintiff Rose Ann Adye was a citizen of the state of Kentucky and resident of Louisville, Kentucky. Plaintiff was prescribed, purchased, and ingested Invokana®.

4. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT L.L.C. f/k/a/ JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT L.L.C. ("JANSSEN R&D") is a limited liability company organized and existing under the laws of New Jersey and has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D's sole member is JANSSEN PHARMACEUTICALS, INC., (Centocor, Inc. [now known as Janssen Biotech, Inc.], a Pennsylvania corporation with its principal place of business and nerve center located at 200 Great Valley Parkway, Malvern, Pennsylvania.), which is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Invokana®. Upon information and belief, and at all relevant times, Defendant, JANSSEN R&D, was in the business of and did research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Invokana® for use as a drug to treat Type 2 Diabetes.

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

6. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("JANSSEN PHARM") is a Pennsylvania Corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and/or marketing of pharmaceutical products including Invokana®. Upon information and belief, and at all relevant times, Defendant, JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Invokana® for treatment of type 2 diabetes.

7. Upon information and belief, Defendant JANSSEN ORTHO LLC ("JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 01, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated in Ireland with a principal place of business in Puerto Rico. Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland, and Puerto Rico for purposes of determining diversity under 28 U.S.C. § 1332. As part of its business, JANSSEN ORTHO is involved in the research, development,

sales, and marketing, and manufacturing of pharmaceutical products including Invokana®. Upon information and belief, and at all relevant times, Defendant, JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Invokana® for use as a drug to treat type 2 diabetes.

8. Upon information and belief, Defendant MITSUBISHI TANABE PHARMA CORPORATION ("MTPC") is a corporation organized and existing under the laws of Japan, having an office and place of business at 2-6-18, Kitahama, Chuo-ku, Osaka 541-8505, Japan. Upon information and belief, Invokana® was first developed by MTPC and later licensed to Janssen Pharmaceuticals.

9. Upon information and belief, Defendants John Does 1-50 are corporations or other legal entities, the names and addresses of residences of which are unknown. At all times alleged herein, Defendants shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

NATURE OF THE CASE

10. Defendants manufactured, marketed, advertised, distributed, promoted, labeled, tested, and sold Invokana® as a drug to treat Type 2 Diabetes.

11. On March 29, 2013, Invokana® was approved by the United States Food and Drug Administration ("FDA") to improve glycemic control in adults with type 2 diabetes.

12. Invokana® was the first member of a new class of antidiabetic drugs known as sodium glucose co-transporter 2 ("SGLT2") inhibitors. SGLT2 inhibitors are designed to inhibit

renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

13. Thought Invokana is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market Invokana® for off label purposes, including, but not limited, to weight loss and reduced blood pressure.

14. Defendants' marketing materials represent that Invokana® is a once-daily pill that is "proven to lower blood sugar (A1C)."[1] Although Defendants explicitly state that Invokana® is not a weight-loss drug, they nevertheless continue to advertise that Invokana® "may help you lose weight."[2]

15. The Institute for Safe Medication Practices' ("ISMP") May 6, 2015 edition of Quarter Watch warns about a number of adverse reactions being reported about Invokana®. In the first year after Invokana® was released, more than 450 serious adverse event reports were filed. Many of these reports were related to kidney failure, including fifty-four reports of kidney failure or impairment, fifty-four cases of severe dehydration or fluid imbalance, eleven cases of kidney stones, and fifty-two cases of abnormal weight loss.[3]

16. Defendants' warning information for Invokana® does not adequately address the increased risk of diabetic ketoacidosis or kidney failure, merely stating that a "possible side effect" of Invokana® is "kidney problems."[4]

[1] What Is Invokana, (last visited Oct. 19, 2015), http://www.invokana.com/about-invokana/what-is-invokana.
[2] *Id.*
[3] http://www.ismp.org/quarterwatch/pdfs/2014Q2.pdf
[4] http://www.invokana.com/medication-guide.pdf

17. Due to the defective nature of Invokana®, persons who were prescribed and ingested it, for even a brief period of time, including the Plaintiff, were at increased risk for developing serious, and sometimes life-threatening, complications, including kidney failure. Defendants withheld and concealed their knowledge that Invokana® can cause serious, and sometimes life-threatening, complications, including kidney failure from the Plaintiff, other consumers, their physicians, the medical community at large and the general public. The Defendants did not adequately warn of increased risk of kidney failure and other serious complications associated with Invokana®, merely indicating that there was a risk for kidney problems, without addressing the specific increased risk of kidney failure or the extent of that risk associated with Invokana®.

18. Other safer available alternatives to Invokana® are available for the treatment of type 2 diabetes.

19. Even though safer alternatives to Invokana® are available, consumers, including Plaintiff, who have used Invokana® for the treatment of Type 2 Diabetes have not been adequately warned about the significant risks and lack of benefits associated with Invokana®.

20. Invokana® is unreasonably dangerous and defective as formulated, putting consumers, including Plaintiff, at an unreasonable risk of suffering injury and death.

21. As the developers, manufacturers and distributers of Invokana®, Defendants knew or should have known that it was associated with serious complications, including kidney failure.

22. Defendants continued to promote Invokana® as a safe and effective treatment for patients with Type 2 Diabetes despite having knowledge of serious complications, including kidney failure associated with it.

23. In 2014 alone, $19.8 million was spent to market Invokana® to doctors and hospitals, making that the second highest amount spent for any pharmaceutical drug in 2014.[5]

24. Defendants have reaped financial success from Invokana® while placing consumers at risk of severe injury and death. Johnson and Johnson reported 2014 domestic sales of Invokana® of $569 million. As of June 2015 domestic sales had reached a total $266 million.

25. Due to the defects in design and warnings, the Invokana® ingested by Plaintiff was unreasonably dangerous at the time it left Defendants' control. The increased risks and subsequent injuries associated with Plaintiff's Invokana® use were the direct and proximate result of Defendants' conduct.

PLAINTIFF'S EXPERIENCE AND INJURIES

26. Plaintiff Rose Ann Adye began using Invokana® as prescribed by her physician for the treatment of Type 2 Diabetes on or around November 1, 2014.

27. After taking Invokana®, on or around February 19, 2015 Plaintiff was admitted to the Jewish Hospital for acute kidney injury and acute kidney failure. Plaintiff would not have used Invokana® had Defendants properly disclosed the risks associated with its use, as safer alternatives were available.

COUNT I

STRICT LIABILITY

28. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

29. Plaintiff pleads this Court in the broadest sense possible, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident state.

[5] Robert Langreth and Caroline Chen, Drug Dollars Seek to Convince Doctors That 2nd Choice Is OK, Bloomberg Business (July 2, 2015 11:18 AM), http://www.bloomberg.com/news/articles/2015-07-02/doctors-attract-most-cash- from-drugmakers-for-diabetes-clotting.

30. At the time of Plaintiff's injuries, Invokana® was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

31. At all times relevant, 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®, that was used by Plaintiff.

32. Invokana® was expected to and did reach the Plaintiff without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

33. 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 its design or formulation, it was more dangerous than an ordinary consumer would expect, and it was unreasonably dangerous to its intended users.

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

35. Plaintiff could not, by the exercise of reasonable care, have discovered Invokana's® defects herein alleged and perceived its danger.

36. 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.

37. Plaintiff's use of Invokana® was appropriate for the purpose for which it was designed, marketed and distributed, and was in the manner normally intended, namely to help lower blood sugar in adults with Type 2 Diabetes.

38. The Invokana® designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as they knew or should have known it created an unreasonable risk of serious and dangerous side effects including, increased risk of kidney failure, as well as other severe consequences which are permanent and lasting in nature and about which the Defendants failed to warn.

39. Invokana® was defective due to Defendants' inadequate post-marketing surveillance and/or their inadequate warnings because after Defendants knew or should have known of the risks of serious side effects including the increased risk of kidney failure, 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®.

40. Defendants are strictly liable for Plaintiff's 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 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®; and d) Defendants failed to adequately test Invokana®.

41. As a direct and proximate result of the foregoing, Defendants are strictly liable to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Invokana®.

42. Defendants' defective design, manufacturing defect, and inadequate warnings regarding Invokana® were acts that amount to willful, wanton, and/or reckless conduct by Defendants, warranting an award of punitive damages.

43. Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT II

DESIGN DEFECT

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

45. Defendants were engaged in the business of designing, manufacturing, testing, marketing, distributing and selling Invokana® for the sale to, and use by, members of the public. The Invokana® manufactured and designed by Defendants reached Plaintiff without substantial change and was ingested as directed. The Invokana® was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

46. Invokana® is defective in its design, because as designed it is capable of causing serious personal injures such as those suffered by Plaintiff.

47. Invokana® contains defects in its design which render the drug dangerous to consumers, such and Plaintiff, when used as intended or as reasonably foreseeable by

Defendants. The defects render Invokana® more dangerous than other drugs which are designed to treat Type 2 Diabetes and cause an unreasonably increased risk of injury, including, but not limited to, life-threatening kidney complications.

48. Because of the design defects, Invokana® was and is unreasonable dangerous.

49. As a direct and proximate result of the defective and unreasonably dangerous Invokana® product, Plaintiff suffered injuries and damages, including acute kidney failure.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT III

FAILURE TO WARN

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

51. The Invokana® ingested by Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendants because they provided warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, heart attack, stroke, kidney failure, and diabetic ketoacidosis.

52. The Invokana® ingested by Plaintiff was used for its intended purpose.

53. Defendants knew or reasonably should have known that the warnings provided to users of Invokana® regarding the risks associated with its use were incorrect and misleading

because they failed to include sufficiently warn of significant possible side effects associated with its use and the comparative severity, incidence, and duration of such adverse effects.

54. Plaintiff did not have the same knowledge as Defendants about these significant possible side effects and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's physician.

55. The Defendants had a continuing duty to warn Plaintiff or her doctors of the dangers associated with Invokana®.

56. Despite the fact that Defendants knew or should have known that Invokana® caused unreasonable and dangerous side effects, they continued to promote and market Invokana® without stating that there were safer, equally effective alternative drug products and/or providing adequate clinically relevant information and data.

57. As a direct and proximate result of the Defendants' failure to warn, Plaintiff has sustained serious and permanent injuries, including acute kidney failure.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT IV

NEGLIGENCE

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

59. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing, labeling, and distribution of Invokana®.

60. Defendants failed to exercise reasonable care in the design of Invokana® because as designed, it is capable of causing serious adverse reactions such as those suffered by Plaintiff. Defendants also failed to exercise reasonable care in the marketing and labeling of Invokana® because they failed to warn, that as designed, Invokana® was capable of causing serious adverse reactions such as those suffered by Plaintiff.

61. Defendants were negligent in, but not limited to, designing, manufacturing and selling Invokana® by, *inter alia*, a) failing to use due care in developing, testing, designing and manufacturing Invokana® to avoid the aforementioned risks; b) failing to accompany Invokana® with proper or adequate warnings, or labeling regarding adverse risks associated with its use; c) designing, manufacturing and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Plaintiff; d) failing to remove Invokana® from the market when Defendants knew or should have known of the likelihood of serious side effects and injury to its users; e) failing to adequately warns users, consumers and physicians about the severity, scope and likelihood of serious complications, including, but not limited to, heart attack, stroke, kidney failure, and diabetic ketoacidosis while taking Invokana®; and f) representing to physicians that Invokana® was safe and effective for use.

62. As a direct and proximate result of the foregoing negligence of Defendants, Plaintiff has suffered pain, hospitalization, and surgery.

63. Defendants' failure to exercise reasonable care in the design, study, development, manufacture, promotion, sale and marketing of Invokana® was a proximate cause of Plaintiff's injuries.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT V

BREACH OF EXPRESS WARRANTY

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

65. Defendants researched, developed, designed, tested, manufactured, distributed, marketed, sold and/or otherwise released into the stream of commerce Invokana®, and directly marketed the product to consumers and healthcare professionals, including Plaintiff.

66. Invokana® materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning its properties and effects. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, concerning Invokana® sold to Plaintiff.

67. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered serious injury, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed Invokana® for Plaintiff.

68. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff was exposed to Invokana®, and Plaintiff suffered and continues to suffer from the injuries and damages described in this complaint

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT VI

BREACH OF IMPLIED WARRANTY

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

70. Defendants impliedly warranted to Plaintiff and all others similarly situated that Invokana® was reasonably fit for its intended use and it was designed, manufactured and sold in accordance with good design, engineering and industry standards.

71. Invokana® was defective in its manufacture or design and was therefore not fit for its intended use, and was not designed, manufactured or sold in accordance with good design, engineering and industry standards.

72. Defendants breached the above warranties in that the Invokana® was: a) defective as set forth above, b) was not fit for its intended use, and c) was not designed, manufactured or sold in accordance with good design, engineering and industry standards.

73. As a direct and proximate result of the foregoing breaches of implied warranties, Plaintiff suffered severe injuries, when Plaintiff ingested Invokana® in reasonable reliance upon the implied warranties.

74. Plaintiff's losses and injuries are permanent and continuing.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT VII

FRAUD

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

76. Defendants owed a duty to provide accurate and complete information regarding Invokana®.

77. Defendants knew or should have known that Invokana® caused serious complications, including, but not limited to kidney failure.

78. Despite their knowledge, Defendants omitted material facts in advertisements and other materials available to the public, including Plaintiff and Plaintiff's physician, concerning the safety of Invokana®.

79. Defendants intentionally made false and/or misleading representations of material facts, and omitted material facts from the consuming public, including Plaintiff and Plaintiff's physician, concerning the safety of Invokana®.

80. Defendants' marketing and sale of Invokana® continues to place consumers of Invokana® at risk for serious injuries.

81. Defendants' statements and omissions were made with the intent that members of the public, including Plaintiff and Plaintiff's physician, would rely on them.

82. As a direct and proximate result of the Defendants' acts of fraud, Plaintiff suffered serious injuries including, but not limited to kidney failure.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT VIII

MISREPRESENTATION

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

84. The Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, the FDA, and the public in general, that Invokana® had been tested and was found to be safe and/or effective. These representations were, in fact, false.

85. When these representations were made, Defendants either knew they were false or willfully, wantonly and recklessly disregarded whether they were true.

86. Defendants made these representations with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community, and were intended to induce the medical and healthcare community in particular, to recommend, prescribe, dispense and the general public to purchase Invokana®, both of which evinced a reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the general public.

87. At the time the aforesaid representations were made by the Defendants and at the time Plaintiff used Invokana®, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

88. In reliance upon these representations, Plaintiff was induced to and did use Invokana®, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

89. Defendants knew and were aware or should have been aware that Invokana® had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

90. Defendants knew or should have known that Invokana® had a potential to, could, and would cause severe and grievous injury to its users, and that it was inherently dangerous in a manner that exceeded any warnings.

91. Defendants acted fraudulently, wantonly, and maliciously to the detriment of the Plaintiff and the general public. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff was caused to suffer serious and dangerous side effects including kidney failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT IX

FRAUDULENT CONCEALMENT

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

93. At all times during the course of dealing between Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Invokana® for its intended use.

94. Defendants knew or were reckless in not knowing that its representations were false.

95. Defendants fraudulently concealed and intentionally omitted that Invokana® was not as safe as other drugs for the treatment of Type 2 Diabetes; and that the risks of serious

complications with Invokana® were higher than those with other forms of treatment for Type 2 Diabetes.

96. Defendants were under a duty to disclose to Plaintiff, Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Invokana®, including but not limited to the heightened risks of kidney failure.

97. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects.

98. Defendants' concealment and omissions of material facts concerning the safety of Invokana® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, Plaintiff's physicians, hospitals and healthcare providers inducing their reliance on the misrepresentations, their continued use of Invokana®, and to cause them to purchase, prescribe, dispense and/or use Invokana®.

99. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the existence of Defendants' concealment and omissions.

100. As a direct and proximate result of one or more of the wrongful concealment or omissions of the Defendants, Plaintiff was caused to suffer serious and dangerous side effects including kidney failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT X

NEGLIGENT MISREPRESENTATION

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

102. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, the Plaintiff and the public, that Invokana® had not been adequately tested and found to be safe and effective. Defendants knew, or should have known, that there were dangerous side effects resulting from the use of Invokana®.

103. Defendants failed to exercise ordinary care in making representations concerning Invokana® while they were involved its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because they negligently misrepresented its unreasonably high risk of dangerous, adverse side effects, including kidney failure and diabetic ketoacidosis.

104. Defendants concealed material information, including adverse information regarding the safety and effectiveness of Invokana®.

105. Defendants misrepresented their insufficiency of testing which, if properly performed, would have shown that Invokana® had serious side effects.

106. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants as set forth herein, Plaintiff suffered serious injuries, including acute renal failure.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT XI

VIOLATION OF THE FAIR BUSINESS PRACTICES ACT OF 1975

(O.C.G.A. § 10-1-390, *et seq.*)

107. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

108. Plaintiff pleads 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.

109. Plaintiff is a "consumer" under the Fair Business Practices Act of 1975.

110. Invokana® is merchandise or goods under the Fair Business Practices Act of 1975.

111. Defendants are merchants engaged in "consumer acts or practices" and "consumer transactions" in "trade or commerce" under the Fair Business Practices Act of 1975.

112. Defendants' sale of Invokana® constitutes an unfair and/or deceptive trade practice in violation of O.C.G.A. § 10-1-390, *et seq*. in that Defendants advertised and promised that Invokana® was of a particular standard, quality, or grade when in fact it was not.

113. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, acute renal failure, 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.

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

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

116. 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 its safety, its efficacy, its usefulness. Defendants made these misrepresentations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff.

117. Defendants' conduct was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because they 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®.

118. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT XII

PUNITIVE DAMAGES

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

120. At all times relevant, Defendants knew or were recklessly indifferent in not knowing that Invokana® was inherently dangerous with respect to the risk of kidney failure.

121. Defendants misrepresented facts concerning the safety of Invokana® by making false representations about and concealing information regarding Invokana®. Defendants misrepresented and downplayed the risks of serious injuries including kidney failure and diabetic ketoacidosis associated with the use of Invokana®.

122. Defendants' actions were performed intentionally, willfully, wantonly, and/or purposefully on Plaintiff.

123. Defendants continued to promote the safety of Invokana®, even after they knew of the risks associated with it.

124. Defendants' conduct was committed with wanton and willful disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff respectfully demands that this Honorable Court enter judgment against Defendants, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for damages allowable by law against Defendants together with interest, costs and attorney's fees as well as all such other relief as the Court may deem proper.

DEMAND FOR A JURY TRIAL

Plaintiff respectfully demands a trial by jury on all Counts and as to all issues.

RESPECTFULLY SUBMITTED,

SCHACHTER HENDY & JOHNSON, P.S.C.

Dated: 02/19/2016

/s/Ronald E. Johnson, Jr.
RONALD E. JOHNSON, JR. (88302)
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JS 44 (Rev. 12/12)

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

Rose Ann Adye,

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

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

DEFENDANTS

Janssen Research & Development L.L.C., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Ortho L.L.C., Mitsubishi Tanabe Pharma Corporation, and John Does 1-50,

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

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

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 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 $ 75,001.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.