UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

David C. Lessard, *Plaintiff,* vs. JANSSEN PHARMACEUTICALS, INC. a Pennsylvania corporation, Serve: CT Corporation System 208 S. LaSalle St., Suite 814 Chicago, IL 60604 and JOHNSON & JOHNSON CO., a New Jersey corporation Serve: One Johnson & Johnson Plaza New Brunswick, NJ 08933 and MITSUBISHI TANABE PHARMA CORP., a Japanese corporation, Serve: 3-2-10, Dosho-machi, Chu-ku Osaka 541-8505, Japan *Defendants*.	)	Case No. **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, by and through the undersigned counsel, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and the Defendants.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants conduct substantial business in this District.

3. This Court has personal jurisdiction over the Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, have substantial and continuing contact with the State of Louisiana, and derive substantial revenue from goods used and consumed within the State of Louisiana. The Defendants actively sell, market and promote its pharmaceutical product INVOKANA to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

4. This action is brought on behalf of DAVID LESSARD ("Plaintiff"). Plaintiff used INVOKANA, which is a medication used for the treatment of Type 2 diabetes.

5. Defendants, JANSSEN PHARMACETUICALS, INC., JOHNSON & JOHNSON CO., AND MITSUBISHI TANABE PHARMA CORP., (hereinafter collectively referred to as "Defendants") directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold INVOKANA for the treatment of type 2 diabetes.

6. Defendants concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

7. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including diabetic ketoacidosis.

8. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed diabetic ketoacidosis. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff.

9. This is an action for product liability, design defect, failure to warn, negligence, fraud, misrepresentation, and breach of warranties against Mitsubishi Tanabe Pharma Corp. ("TANABE"), Johnson & Johnson, Co ("JOHNSON & JOHNSON"), and Janssen Pharmaceuticals ("JANSSEN").

10. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTY PLAINTIFF

11. Plaintiff DAVID LESSARD, at all times relevant hereto, is a citizen and resident of the State of Louisiana and is domiciled in the Town of Slidell, Parish of St. Tammany, State of Louisiana.

12. Upon information and belief, Plaintiff was prescribed INVOKANA in the State of Louisiana in or around May 2015, upon direction of his physician for the treatment of Type 2 diabetes.

13. Upon information and belief, Plaintiff began using INVOKANA in or around June 2015 up until approximately July 2015.

14. Upon information and belief, and as a direct and proximate result of the use of Defendants' INVOKANA, Plaintiff developed permanent personal injuries including diabetic ketoacidosis.

15. As a direct and proximate result of the use of Defendants' INVOKANA, Plaintiff suffered serious and dangerous side effects including but not limited to, diabetic ketoacidosis, as well as other severe 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.

16. As a direct and proximate result of Defendants' conduct Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages through third parties or related entities, its products, including the prescription drug INVOKANA.

PARTY DEFENDANTS

17. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania Corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

18. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products including INVOKANA.

19. Upon information and belief, Defendant, JANSSEN PHARM, has transacted and conducted business in the State of Louisiana.

20. Upon information and belief, Defendant, JANSSEN PHARM, has derived substantial revenue from goods and products used in the State of Louisiana.

21. Upon information and belief, Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

22. 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 distribute the drug INVOKANA for use as Type 2 diabetes treatment.

23. Upon information and belief, Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

24. As part of its business, JOHNSON & JOHNSON is involved in the research, development, sales, and marketing of pharmaceutical products including INVOKANA.

25. Upon information and belief, Defendant, JOHNSON & JOHNSON has transacted and conducted business in the State of Louisiana.

26. Upon information and belief, Defendant, JOHNSON & JOHNSON, has derived substantial revenue from goods and products used in the State of Louisiana.

27. Upon information and belief, Defendant, JOHNSON & JOHNSON, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

28. Upon information and belief, and at all relevant times, Defendant, JOHNSON & JOHNSON, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug INVOKANA for use as Type 2 diabetes treatment.

29. Upon information and belief, Defendant TANABE is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chu-ku, Osaka 541-8505, Japan.

30. Upon information and belief, Defendant, TANABE has transacted and conducted business in the State of Louisiana.

31. Upon information and belief, Defendant, TANABE, has derived substantial revenue from goods and products used in the State of Louisiana.

32. Upon information and belief, Defendant, TANABE, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

33. Upon information and belief, and at all relevant times, Defendant, TANABE, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug INVOKANA for use as Type 2 diabetes treatment.

FACTUAL BACKGROUND

34. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute INVOKANA as a type 2 diabetes treatment.

35. Defendant TANABE, in collaboration with Defendant JOHNSON & JOHNSON, designed and developed the diabetes drug, INVOKANA.

36. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, 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 Louisiana.

37. INVOKANA is one of Defendants' top selling drugs, with sales of $278 million in just the first quarter of 2015.

38. In March 2013, the United States Food and Drug Administration ("FDA") approved Defendants' compound INVOKANA (*canagliflozin*) for the treatment of type 2 diabetes.

39. *Canagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 ("SGLT2") inhibitors, and is marketed in the United States by Defendants under the name INVOKANA.

40. SGLT2 inhibitors, including INVOKANA, primarily are used for treating type 2 diabetes. INVOKANA was the first SGLT2 inhibitor approved for use by the FDA.

41. SGLT2 inhibitors, including INVOKANA, 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.

42. Though 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, reduced blood pressure, and improved glycemic control in type 1 diabetics.

43. Since INVOKANA's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of INVOKANA.

44. An analysis of the FDA adverse event database shows that patients taking INVOKANA are several times more likely to report diabetic ketoacidosis than those taking nonSGLT2 diabetes drugs to treat type 2 diabetes.

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

46. Consumers, including Plaintiff, who have used INVOKANA for treatment of diabetes, have several alternative safer products available to treat the conditions.

47. Defendants knew of the significant risk of diabetic ketoacidosis caused by ingestion of INVOKANA. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff or the medical community, of the severity of such risks.

48. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of INVOKANA and willfully deceived Plaintiff, his health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the INVOKANA.

49. As a direct result, in or about June 2015, Plaintiff was prescribed and began taking INVOKANA, primarily to treat type 2 diabetes.

50. Plaintiff ingested and used INVOKANA as prescribed and in a foreseeable manner.

51. The INVOKANA used by Plaintiff was provided to him in a condition substantially the same as the condition in which it was manufactured and sold.

52. Plaintiff agreed to initiate treatment with INVOKANA in an effort to reduce his blood sugar. In doing so, Plaintiff relied on claims made by Defendants that INVOKANA was safe and effective for the treatment of diabetes.

53. Instead, INVOKANA can cause severe injuries, including diabetic ketoacidosis.

54. After beginning treatment INVOKANA, and as a direct and proximate result thereof, Plaintiff suffered diabetic ketoacidosis.

55. Defendants knew or should have known the risks associated with the use of INVOKANA, including the risk of developing diabetic ketoacidosis.

56. The development of Plaintiff's 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.

57. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's defects.

58. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold

INVOKANA without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

59. Plaintiff would not have used INVOKANA had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with INVOKANA, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA.

60. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking INVOKANA.

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

62. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has 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. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

63. Plaintiff has suffered from mental anguish from the knowledge that he may suffer life-long complications as a result of the injuries caused by INVOKANA.

FIRST CAUSE OF ACTION
DESIGN DEFECT UNDER LA. R.S. 9:2800.56
(PRODUCTS LIABILITY)

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

65. INVOKANA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

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

67. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to permanent personal injuries;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making the use of INVOKANA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market;

c. INVOKANA's design defects existed before it left the control of the Defendants;

d. INVOKANA was insufficiently tested;

e. INVOKANA caused harmful side effects that outweighed any potential utility; and

f. INVOKANA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

68. 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.

69. 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.

70. 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.

71. At the time of the Plaintiff's use of INVOKANA, INVOKANA was being used for the purposes and in a manner normally intended, namely to reduce the treatment of type 2 diabetes.

72. Defendants, with this knowledge, voluntarily designed INVOKANA in a dangerous condition for use by the public, and in particular the Plaintiff.

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

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

75. 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.

76. 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.

77. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

78. The Plaintiff could not, by the exercise of reasonable care, have discovered INVOKANA's defects herein mentioned and perceived its danger.

79. Said defects in Defendants' drug INVOKANA were a substantial factor in causing Plaintiff's injuries.

80. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, diabetic ketoacidosis, 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.

81. 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.

82. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION
INADEQUATE WARNING UNDER LA. R.S. 9:2800.57
(PRODUCTS LIABILITY)

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

84. INVOKANA was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, and his health care providers, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause permanent physical injuries and side effects, notwithstanding the Defendants' knowledge of

an increased risk of these injuries and side effects. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as provided pursuant to La.R.S. 9:2800.57.

85. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury.

86. Plaintiff was prescribed and used the subject product for its intended purpose.

87. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

88. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

89. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

90. Defendants communicated to health care professional's 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 acid-base balance; and

e. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of INVOKANA.

91. Plaintiff, individually and through his prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

92. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

93. Had Plaintiff received adequate warnings regarding the risks of the subject product, he would not have used it.

94. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, diabetic ketoacidosis, 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.

95. 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.

96. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION
WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE

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

98. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and his healthcare providers.

99. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

100. Plaintiff therefore asserts claims for exemplary damages.

101. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

102. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of INVOKANA. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of INVOKANA, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting INVOKANA, despite their knowledge and awareness of these serious side effects and risks.

103. Defendants had knowledge of, and were in possession of evidence demonstrating that INVOKANA caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of INVOKANA.

104. Although Defendants knew or recklessly disregarded the fact that INVOKANA causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute INVOKANA to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating type 2 diabetes.

105. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing INVOKANA and consumers from purchasing and ingesting INVOKANA, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming INVOKANA.

106. Defendants knew of INVOKANA's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by INVOKANA.

107. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other INVOKANA users and for the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

108. Prior to the manufacture, sale, and distribution of INVOKANA, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of INVOKANA to risk of injury or death.

109. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in INVOKANA and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of INVOKANA knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

110. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

FOURTH CAUSE OF ACTION
NEGLIGENCE

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

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

113. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, 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 Plaintiff and other consumers of the dangers associated with INVOKANA.

114. 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.

115. Defendants had a duty to disclose to health care professionals the causal relationship or association of INVOKANA to the development of Plaintiff's injuries.

116. 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 Plaintiff.

117. 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 Plaintiff.

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

119. Defendants knew that many health care professionals were prescribing INVOKANA, and that many patients developed serious side effects including but not limited to diabetic ketoacidosis.

120. 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 know that a consumer's use and ingestion of INVOKANA created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

121. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, 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.

122. 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 INOKANA to consumers, including Plaintiff, 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 acid-base balance;

g. failing to exercise due care when advertising and promoting INVOKANA; and

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

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

124. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of INVOKANA.

125. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

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

127. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related

health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY UNDER LA. R.S. 9:2800.58
(PRODUCTS LIABILITY)

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

129. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold INVOKANA and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold INVOKANA, as a treatment for type 2 diabetes.

130. Defendants expressly represented to Plaintiff, other consumers, and the medical community that INVOKANA was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

131. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects and causes severe and permanent injuries.

132. At the time of the making of the express warranties, Defendants knew or should have known of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of the defendants as provided by La. R.S. 9:2800.58.

133. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

134. At all relevant times INVOKANA did not perform as safely as an ordinary consumer and the medical community would expect, when used as intended or in a reasonably foreseeable manner.

135. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

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

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects, and

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

137. The Defendants herein breached the aforesaid express warranties, as their drug INVOKANA was defective.

138. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and/or the FDA that INVOKANA was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for type 2 diabetes, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

139. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that INVOKANA was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

140. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, diabetic ketoacidosis, 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.

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

142. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

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

144. The Defendants impliedly represented and warranted to the users of I and their physicians, healthcare providers, and/or the FDA that INVOKANA was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

145. 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.

146. Defendants were aware that consumers, including Plaintiff, would use INVOKANA in the manner intended.

147. Plaintiff 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.

148. Defendants breached the implied warranty to consumers, including Plaintiff, as INVOKANA was not of merchantable quality or safe and fit for its intended use.

149. Consumers, including Plaintiff and the medical community, reasonably relied upon Defendants' implied warranty for INVOKANA.

150. INVOKANA reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

151. That said representations and warranties aforementioned were false, misleading, and inaccurate in that INVOKANA was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

152. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether INVOKANA was of merchantable quality and safe and fit for its intended use.

153. INVOKANA was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

154. The Defendants herein breached the aforesaid implied warranties, as their drug INVOKANA was not fit for its intended purposes and uses.

155. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, diabetic ketoacidosis, 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.

156. 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.

157. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION
REDHIBITION

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

159. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

160. Defendants sold and promoted INVOKANA, which Defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product, sold and promoted by Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the subject product.

161. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.

162. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, under

Louisiana law, Defendants are deemed to know that INVOKANA possessed a redhibitory defect. La. C.C. art. 2545.

163. As a result of the product's redhibitory defects, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, diabetic ketoacidosis, 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.

164. As a result of the product's redhibitory defects, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

165. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein and has incurred attorneys' fees which he is entitled to recover from Defendants.

EIGHTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

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

167. 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 type 2 diabetes; and

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

168. 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 Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

169. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and his physicians, rely upon them.

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

171. Plaintiff, his doctors, and others relied upon these representations.

172. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

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

174. 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.

175. 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.

176. 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.

177. 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 Plaintiff.

178. 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.

179. 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 regarding the safety of INVOKANA. Defendants made material misrepresentations to Plaintiff, 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 type 2 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; and

c. misrepresenting INVOKANA's risk of unreasonable, dangerous, adverse side effects.

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

181. 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.

182. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of INVOKANA.

183. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that INVOKANA had been tested and found to be safe and effective for treating type 2 diabetes.

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

185. 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.

186. 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.

187. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. 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.

188. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

TENTH CAUSE OF ACTION
NEGLIGENT DESIGN

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

190. At all relevant times, Defendants owed a duty to consumers, including Plaintiff and his health care professionals, to exercise reasonable care in the design of INVOKANA.

191. Defendants negligently and carelessly breached this duty of care to Plaintiff because INVOKANA was and is unreasonably defective in design as follows:

a. INVOKANA unreasonably increased the risks of developing Plaintiff's injuries as complained of herein;

b. INVOKANA was not reasonably safe as intended to be used;

c. INVOKANA was more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. INVOKANA contained insufficient, incorrect, and defective warnings in that it failed to alert health care professionals and users, including Plaintiff, of the severity of the risks of adverse effects;

e. INVOKANA was not safe for its intended use;

f. INVOKANA was not adequately tested; and/or

g. INVOKANA's risks exceeded any benefit of the drug;

192. Defendants' INVOKANA was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

193. At all times relevant hereto, INVOKANA was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

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

195. Plaintiff used INVOKANA for its intended purposes and in a manner normally intended: to primarily treat type 2 diabetes.

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

197. At the time INVOKANA left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of INVOKANA. This was demonstrated by the existence of other type 2 diabetes medications that had a more established safety profile and a considerably lower risk profile.

198. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of INVOKANA and perceived its danger.

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

200. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

ELEVENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

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

202. 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.

203. 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; and

b. Upon information and belief, 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.

204. Defendants were under a duty to Plaintiff 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 Plaintiff.

205. 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 Plaintiff and his healthcare providers. As such, Plaintiff and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

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

207. 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.

208. The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA.

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

210. 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.

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

212. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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.

Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

TWELFTH CAUSE OF ACTION
FRAUD

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

214. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, his prescribing health care professionals, the health care industry, and consumers that INVOKANA had been adequately tested in clinical trials and was found to be safe and effective as a type 2 diabetes treatment.

215. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of INVOKANA. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of INVOKANA, such as Plaintiff.

216. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and

his prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase INVOKANA, despite the risk of severe life threatening injury, which Defendants knew were caused by the products.

217. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks.

218. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of INVOKANA.

219. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with INVOKANA from physicians and patients, including Plaintiff and his prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the INVOKANA. For example:

a. INVOKANA was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of INVOKANA does not result in a safe and more effective method of type 2 diabetes treatment than other available treatments;

c. The risks of harm associated with the use of the INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with INVOKANA was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff relied when ingesting INVOKANA;

f. The limited clinical testing revealed that INVOKANA had an unreasonably high risk of injury, including Plaintiff's injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of INVOKANA, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using INVOKANA could suffer diabetic ketoacidosis and sequelae; and/or

j. INVOKANA was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

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

dangerous injuries and damages to persons who ingest INVOKANA, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

221. Defendants' intentional concealment and omissions of material fact concerning the safety of INVOKANA was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause. Plaintiff's prescribing health care professionals to purchase, prescribe, and/or dispense INVOKANA, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that INVOKANA was a safe and effective diabetes drug therapy.

222. At the time Plaintiff purchased and used INVOKANA, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of INVOKANA's safety and efficacy.

223. Defendants knew and had reason to know that INVOKANA could and would cause serious personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

224. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to use and in fact used INVOKANA, thereby sustaining injuries and damages. Defendants knew and had reason to know that Plaintiff and his health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and his health care professionals would not have prescribed

and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

225. During the marketing and promotion of INVOKANA to health care professionals, neither Defendants nor the co-promoters who were detailing INVOKANA on Defendants' behalf, warned health care professionals, including Plaintiff's prescribing health care professionals, that INVOKANA caused or increased the risk of harm of diabetic ketoacidosis.

226. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of INVOKANA.

227. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that INVOKANA was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

228. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. Defendants knew of INVOKANA's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

229. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses.

Plaintiff 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. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.
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 determined at trial of this action;
3. Pain and suffering;
4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;
5. Punitive damages;
6. Prejudgment interest at the highest lawful rate allowed by law;
7. Interest on the judgment at the highest legal rate from the date of judgment until collected;
8. Attorneys' fees, expenses, and costs of this action; and
9. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff demands trial by jury on all of the triable issues within this Petition.

Dated: December 16, 2015

/s/ Michael Hingle
Michael Hingle, T.A. #6943
Bryan A. Pfleeger, LA Bar #23896
Julie M. Jochum, LA Bar #33463
220 Gause Boulevard
Slidell, LA 70458
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Counsel for Plaintiff

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

DAVID C. LESSARD

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
MICHAEL HINGLE OF MICHAEL HINGLE & ASSOCIATES
220 GAUSE BLVD. SLIDELL, LA 70458
(985) 641-6800

DEFENDANTS

JANSSEN PHARMACEUTICALS, INC.

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)*

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

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

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

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

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

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:
PERSONAL INJURIES DUE TO DEFENDANT'S DEFECTIVE PRODUCT INVOKANA

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
03/17/2016

SIGNATURE OF ATTORNEY OF RECORD
/S/ MICHAEL HINGLE

FOR OFFICE USE ONLY

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

David C. Lessard

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., JOHNSON AND JOHNSON CO., and MITSUBISHI TANABE PHARMA CORP.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* JOHNSON & JOHNSON CO.,
a New Jersey corporation,
Serve: One Johnson & Johnson Plaza
New Brunswick, NJ 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

David C. Lessard

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., JOHNSON AND JOHNSON CO., and MITSUBISHI TANABE PHARMA CORP.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* JANSSEN PHARMACEUTICALS, INC.
a Pennsylvania corporation,
Serve: CT Corporation System
208 S. LaSalle St., Suite 814
Chicago, IL 60604

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: