IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

Luana Jean Collie, Plaintiff, v. JANSSEN RESEARCH & DEVELOPMENT, LLC; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON CO.; and MITSUBISHI TANABE PHARMA CORP., Defendants.	)	CIVIL ACTION NO. COMPLAINT JURY DEMANDED

COMPLAINT AND JURY DEMAND

Plaintiff, Luana Jean Collie ("Plaintiff"), by and through the undersigned counsel hereby submits this Complaint and Jury Demand against Janssen Research & Development, LLC, Janssen Pharmaceuticals, Johnson & Johnson Co., and Mitsubishi Tanabe Pharma Corp. ("Defendants"), for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff as a result of her injuries suffered as the direct and proximate result of taking the prescription drug INVOKANA®, also known as *canagliflozin*. In support of this Complaint, Plaintiff alleges the following.

INTRODUCTION

1. 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 diabetes.

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

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

4. 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.

5. This is an action for product liability, design defect, failure to warn, negligence, fraud, misrepresentation, and breach of warranties against Janssen Research & Development, LLC ("Janssen R&D"), Janssen Pharmaceuticals ("Janssen"), Johnson & Johnson Co. ("Johnson & Johnson"), and Mitsubishi Tanabe Pharma Corp. ("Tanabe").

6. 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.

PARTIES

7. Plaintiff, Luana Jean Collie, is a citizen and resident of Orange Beach, Baldwin County, Alabama.

8. Defendant Janssen Research & Development LLC ("Janssen R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at 920 Route 202, Raritan NJ 08869. Janssen R&D's sole member is Janssen Pharmaceuticals, Inc.

9. Defendant Janssen Pharmaceuticals, Inc. (Janssen) is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson.

10. Defendant Johnson & Johnson, Inc. ("Johnson & Johnson") is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

11. Defendant Mitsubishi Tanabe Pharma Corp. ("Tanabe") is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

12. At all times herein mentioned, Defendants researched, designed, developed, licensed, manufactured, advertised, promoted, distributed, supplied, sold, and introduced into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the pharmaceutical product, INVOKANA.

JURISDICTION AND VENUE

13. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

14. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

15. Defendant Tanabe, in collaboration with Defendant Johnson & Johnson, designed and developed the diabetes drug, INVOKANA.

16. 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 Alabama.

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

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

19. *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.

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

21. 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.

22. Though INVOKANA is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continued 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.

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

24. 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 non-SGLT2 diabetes drugs to treat diabetes.

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

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

27. 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.

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

29. As a direct result, in or about December 2014, Plaintiff was prescribed and began taking INVOKANA, primarily to treat diabetes.

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

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

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

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

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

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

36. 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.

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

38. 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, including but not limited to the risk of developing diabetic ketoacidosis.

39. 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.

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

41. As a result of Defendants' actions, Plaintiff and her 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.

42. 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.

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

FIRST CAUSE OF ACTION
NEGLIGENCE

44. 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.

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

46. 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.

47. 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.

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

49. 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.

50. 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.

51. 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 if the products.

52. 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.

53. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, sale, testing, quality assurance, quality control, and distribution of INVOKANA in interstate commerce, in that Defendants knew and had reason to know that 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.

54. 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.

55. The Defendant's 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 premarketing tests of INVOKANA;

c. Failing to conduct sufficient post-market testing and surveillance of INVOKANA;

d. Designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA to consumers, including 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 and 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.

56. 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.

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

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

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

60. 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 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.

SECOND CAUSE OF ACTION
NEGLIGENCE PER SE

61. 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.

62. Defendants had a duty to exercise reasonable care, and comply with existing laws, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of INVOKANA into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

63. Defendants failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of INVOKANA into interstate commerce in that Defendants knew or should have known that using INVOKANA created an unreasonable risk of dangerous injuries including diabetic ketoacidosis, 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.

64. Defendants, its agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in particular.

65. The laws violated by Defendants were designed to protect Plaintiff and similarly situated persons against the risks and hazards that have actualized in this case. Therefore, Defendants' conduct constitutes negligence per se.

66. Despite the fact that Defendants knew or should have known that INVOKANA significantly increased the risk of injuries, including diabetic ketoacidosis, Defendants continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell INVOKANA to consumers, including Plaintiff.

67. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

68. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

69. Had Plaintiff not taken INVOKANA, Plaintiff would not have suffered the injuries and damages as described herein.

70. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious injuries, including diabetic ketoacidosis, and other injuries that 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.

71. Plaintiff also has sustained severe emotional distress and suffering as a result Defendants' wrongful conduct.

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.

THIRD CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

72. 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.

73. Defendants made fraudulent misrepresentations with respect to INVOKANA in the following particulars:

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

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

74. 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.

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

76. 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.

77. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

78. 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 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.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

79. 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.

80. 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.

81. Defendants disseminated to health care professional 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.

82. 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.

83. 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.

84. 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.

85. 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, Plaintiff's health care professionals, the healthcare community, and the general public, including:

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

b. Concealing, misrepresenting, actively downplaying the severe and life threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative pharmaceutical therapies; and

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

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

87. 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.

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

89. 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 fro treating diabetes.

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

91. 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.

92. 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.

93. 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.

94. 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 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.

FIFTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

95. 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.

96. 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.

97. 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 submission 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.

98. 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.

99. 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 her healthcare providers. As such, Plaintiff and Plaintiff's health care providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

100. 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.

101. 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.

102. 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 Plaintiff's health care providers would prescribe and recommend INVOKANA.

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

104. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff and Plaintiff's physicians would not have prescribed or ingested the drug.

105. Defendants, by concealment or other action, intentionally prevented Plaintiff and her 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.

106. 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 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.

SIXTH CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT (STRICT LIABILTY)

107. 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.

108. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed INVOKANA, including the INVOKANA used by Plaintiff, which was in a defective and unreasonably dangerous condition.

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

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

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

a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous that other risks associated with the treatment of diabetes;

c. INVOKANA was insufficiently tested;

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

e. Defendants were aware at the time INVOKANA was marketed that ingestion of INVOKANA would result in an increased risk of diabetic ketoacidosis, and other injuries;

f. Inadequate post-marketing surveillance; and/or

g. There were safer alternative designs and formulations that were not utilized.

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

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

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

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

116. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that INVOKANA was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

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

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

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

120. The harm caused by INVOKANA far outweighed its benefit, rendering INVOKANA more dangerous than alternative products. Defendants could have designed INVOKANA to make it less dangerous. When Defendants designed INVOKANA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

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

122. Defendants' defective design of INVOKANA was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of INVOKANA. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of INVOKANA.

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

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

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

126. 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 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.

SEVENTH CAUSE OF ACTION
PRODUCTS LIABILITY – FAILURE TO WARN (STRICT LIABILTY)

127. 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.

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

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

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

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

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

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

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

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

136. Defendants had a continuing duty to warn Plaintiff of the dangers associate with INVOKANA.

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

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

139. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that INVOKANA caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of INVOKANA, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

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

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

142. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professions 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 the 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.

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

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

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

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

147. 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 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.

EIGHTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

148. 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.

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

150. 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.

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

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

153. Despite this, Defendants expressly represented that INVOKANA was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and Plaintiff's health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurate nor adequately set forth.

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

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

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

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

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

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

160. 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 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.

NINTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

161. 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.

162. Defendants manufactured, distributed, advertised, promoted, and sold INVOKANA.

163. 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.

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

165. INVOKANA was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA has dangerous propensities when used as intended and can cause serious injuries, including diabetic ketoacidosis, stroke, heart attack, and severe kidney damage.

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

167. Defendants were aware that consumers, including Plaintiff, would use INVOKANA as marketed by Defendants. As such, Plaintiff was a foreseeable user of INVOKANA.

168. Upon information and belief, Plaintiff and/or Plaintiff's health care professionals were at all relevant times in privity with Defendants.

169. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

170. 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.

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

172. Plaintiff and Plaintiffs physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

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

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

175. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

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

177. Neither Plaintiff nor Plaintiff's health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with INVOKANA.

178. Defendants' breach of these implied warranties caused Plaintiff's injuries.

179. 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 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.

TENTH CAUSE OF ACTION
NEGLIGENT DESIGN

180. 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.

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

182. 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 risk of developing Plaintiff's injuries as complained of herein;

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

c. 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;

d. INVOKANA was not safe for its intended use;

e. INVOKANA was not adequately tested; and/or

f. INVOKANA's risks exceeded any benefit of the drug.

183. 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.

184. 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.

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

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

187. The harm caused by INVOKANA far outweighed the benefits, rendering 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.

188. 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 diabetes medications that had a more established safety profile and a considerably lower risk profile.

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

190. 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.

191. 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 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.

ELEVENTH CAUSE OF ACTION
FRAUD

192. 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.

193. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, Plaintiff's 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 diabetes treatment.

194. 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 risks of adverse health events associated with the 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.

195. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and her prescribing health care professionals, so as to induce them to recommend, prescribe, disperse, or purchase INVOKANA, despite the risk of severe life threatening injuries, which Defendants knew were caused by the product.

196. The 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 risk.

197. 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.

198. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with INVOKANA from physicians and patients, including Plaintiff and her 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 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 diabetes treatment than other available treatments;

c. 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;

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/or

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

199. 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 Defendants.

200. 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 physicians 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.

201. 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 a true, complete, and accurate portrayal of INVOKANA's safety and efficacy.

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

203. 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 her health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and her health care professionals would not have prescribed and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

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

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

206. 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.

207. 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.

208. 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 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
PUNITIVE DAMAGES

209. 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.

210. Plaintiff is entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendant misled both the medical community and the public at large, including Plaintiff, by making false representations and concealing pertinent information regarding INVOKANA. Defendants downplayed, understated and disregarded their knowledge of the serious and permanent risks associated with the use of INVOKANA, despite information demonstrating that the product was unreasonably dangerous.

211. The conduct of Defendants in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing INVOKANA, and in failing to warn Plaintiff and other members of the public of the dangers inherent in the use of INVOKANA, which were known to Defendants, was attended by circumstances of malice, avarice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiff.

212. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of INVOKANA.

213. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, and Plaintiff specifically, in the following ways: Defendants continued to promote the safety of INVOKANA, while providing consumers and their health care providers no warnings or insufficient warnings about the risks associated with the use of INVOKANA, even after Defendant knew of the risks.

214. Defendants' conduct was committed knowingly with conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, or with such wanton and/or reckless disregard, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For consequential damages in excess of the jurisdictional minimum of this Court;

e) For compensatory damages in excess of the jurisdictional minimum of this Court;

f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

g) For attorneys' fees, expenses and costs of this action; and

h) For such further and other relief as this Court deems necessary, just and proper.

Dated: December 8, 2015

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