IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

JOAN MULLIN, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON COMPANY; JANSSEN ORTHO, LLC AND MITSUBISHI TANABE PHARMA CORP. Defendants.	)	C.A. No.: Jury Trial Demanded

COMPLAINT

COMMON ALLEGATIONS

A. BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Invokana (also known as canaglitlozin).

B. PARTIES

2. At the time of Plaintiff Joan Mullin's use of Invokana and injuries, Plaintiff was a resident and citizen of Bluff City, Tennessee. Plaintiff is presently a citizen of and resides in Bluff City, Tennessee.

3. 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

One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Janssen R&D's sole member is Janssen Pharmaceuticals, Inc. Janssen R&D has transacted and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware. Janssen Research & Development LLC's address for service of process subject to Del. Code §3104 is: One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

4. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson. Janssen Pharma has transacted and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware. Janssen Pharmaceuticals, Inc.'s address for service of process subject to Del. Code §3104 is: 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

5. Defendant Johnson & Johnson, Inc. (J&J) is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J has transacted and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware. Johnson & Johnson, Inc.'s address for service of process subject to Del. Code §3104 is: One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. Defendant, JANSSEN ORTHO, LLC (hereinafter "Janssen Ortho") is a limited liability corporation organized under laws of Delaware whose registered agent for service of process is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Janssen Ortho's principal place of business is at Stateroad 933 Km 0 1,

Street Statero, Gurabo, Puerto Rico 00778. Janssen Ortho is a subsidiary of Johnson & Johnson. As part of its business, Janssen Ortho is involved in the research, development, sales, and marketing of pharmaceutical products, including Invokana.

7. 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 541-8508, Japan. TANABE is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. Tanabe has transacted and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware.

8. At all times herein mentioned, Defendants advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, Invokana.

9. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, francheres, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

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

11. At all times relevant, Defendants were engaged in the business of developing,

designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, which necessarily includes Delaware, either directly or indirectly through third parties, subsidiaries or related entities, the drug Invokana.

C. FACTUAL ALLEGATIONS

12. This action is for damages brought on behalf of the Plaintiff. Joan Mullin was prescribed, received and has taken the prescription drug Invokana. Ther action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering severe and life-threatening side effects of kidney failure caused by ther drug.

13. Invokana is a member of the glitlozin class of pharmaceuticals, also known as sodium- glucose co-transporter2 ("SGLT2") inhibitors.

14. SGLT2 inhibitors, including Invokana , inhibit renal glucose reabsorption through the SGLT2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract. This puts additional stress on the kidneys in patients already at risk for kidney disease.

15. SGLT2 inhibitors, including Invokana, are designed to target primarily the SGLT2 receptor, but have varying selectivity for ther receptor, and block other sodium-glucose co-transporter receptors, including SGLT1.

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

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

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

19. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Invokana for the use and application by patients with diabetes, including but not limited to, Plaintiff.

20. Defendant Tanabe, in collaboration with the other Defendants, designed and developed the diabetes drug, Invokana.

21. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including Delaware.

22. In May, 2012, Janssen R&D submitted a New Drug Application to the FDA for approval to market Invokana in the United States.

23. In March, 2013, the United States Food and Drug Administration ("FDA") approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

24. As part of its marketing approval of Invokana, the FDA required the defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; and enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamics study and a safety and efficacy study.

25. In an effort to increase sales and market share, Defendants have aggressively

marketed and continue to aggressively market Invokana to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in type 1 diabetics.

26. Defendants also, through their marketing material, misrepresented and exaggerated the effectiveness of Invokana, both as to its ability to lower glucose, and its benefit for non-surrogate measures of health, such as reducing adverse cardiovascular outcomes.

27. Defendants' marketing campaign willfully and internationally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis, kidney failure and cardiovascular injury.

28. Defendants' misrepresentations and off-label advertising campaigns have led to Invokana being prescribed for off-label uses, in people with type 1 diabetes, for weight loss, and reduced blood pressure.

29. Invokana is one of Defendants' top selling drugs, with annual sales exceeding $1billion.

30. At all times herein mentioned, Defendants were authorized to do business within Delaware.

31. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion or the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

32. Defendants misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require

hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

33. Specifically, Defendants knew or should have known or the risks of diabetic ketoacidosis and kidney failure based on the data available to them or that could have been generated by them, including , but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post0mnarketing reports, and regulatory authority investigations, including, but not limited to the following:

a. Invokana selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given Invokana;

c. Studies of phlorizin indicating a propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, indicating a propensity to develop ketoacidosis;

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

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

g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and volume depletion in people taking Invokana;

h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking Invokana;

i. Clinical studies, adverse event reports, and case reports demonstrating re-challenge responses in increasing ketones and diabetic ketoacidosis in people taking Invokana; and

j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking Invokana compared to other glucose- lowering medications.

34. Diabetic Ketoacidosis may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma.

35. Invokana induced diabetic ketoacidosis may lead to delayed treatment because in many cases Invokana will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis. Ther may result in increases progression of the condition and increased injury to the patient.

36. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system.

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

38. 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.

39. Defendants failed to adequately warn consumers and physicians about the risks associated with Invokana and the monitoring required to insure their patients' safety.

40. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not conduct the necessary additional studies to properly evaluate these risks prior to marketing the drug to the general public.

41. Consumers of Invokana and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life-threatening complications thereof.

42. Consumers, including Plaintiff, have several alternative safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

43. Plaintiff was prescribed Invokana by her treating physician and used it as directed.

44. Plaintiff was first prescribed Invokana in order to treat her diabetes on or about December, 2014.

45. While taking Invokana, Plaintiff developed Kidney Failure, Bone Fracture and other injuries as a result of her ingestion of Invokana

46. As a result of Plaintiff's Invokana related injuries, Plaintiff developed serious complications which required multiple days of hospitalization.

47. 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.

48. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

49. Defendants misrepresented that Invokana is a safe and effective treatment for type 2

diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

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

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

52. On information and belief, Defendants withheld material information from the FDA and misrepresented material information regarding the risks and benefits of Invokana in its communications with the FDA. These omissions and misrepresentations included failing to report instances of diabetic ketoacidosis to the FDA, failure to properly categorize adverse events in clinical trials, post-marketing trials, and obtained through its adverse event reporting system, and withholding of relevant information from pre-clinical and clinical trials.

53. On May 15, 2015 the FDA announced that SGLT2 inhibitors may lead to diabetic ketoacidosis.

54. On September 10, 2015, the FDA announced that Invokana causes premature bone loss and fractures.

55. On October 16, 2015, Health Canada, the Canadian drug regulatory authority, announced that Invokana can cause acute kidney injury.

56. On December 4, 2015, the FDA announced a label change for SGLT2 inhibitors, requiring that the label of SGLT2 inhibitors include a warning of ketoacidosis, the risk of too much acid in the blood while taking SGLT2 inhibitors.

57. Prior to the FDA's December 4, 2015 safety announcement, Invokana's label continued to fail to warn consumers of the serious risk of developing diabetic ketoacidosis.

58. The Invokana label currently does not warn of the serious risks of developing bone fractures and kidney injury.

59. Despite the FDA's announcements, Defendants continue to engage in aggressive direct-to-consumer and physician marketing and advertising campaigns for Invokana.

60. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied Invokana to the purchaser.

61. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that Invokana was such a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

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

63. Had Plaintiff and her physicians known the true risks associated with the use of SGLT2 inhibitors, including Invokana, Plaintiff would not have been prescribed Invokana, and Plaintiff would not have taken Invokana, or Plaintiff would have been adequately monitored for

its side effects and as a result would not have suffered injuries and damages from using Invokana.

64. Plaintiff's prescribing and treating physicians relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

65. Plaintiff relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff directly, through print and television advertising, and indirectly through Plaintiff's healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

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

67. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects, and were not reasonably foreseeable to Plaintiff of Plaintiff's physicians.

68. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injury. 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, diminished quality of life, and increased risk of premature death, aggravation of pre existing 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.

69. Plaintiff files her lawsuit within the applicable limitations period of the first suspecting that Invokana caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that he had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of her action. Additionally, Plaintiff was prevented from discovering the information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that the drug Invokana is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

I. CAUSES OF ACTION

Count one- Design Defect (Strict Liability)

70. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

71. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and

unreasonably dangerous condition, including the Invokana used by plaintiff.

72. The design defect was caused by Defendants' failure to:

a. Adequately test Invokana;

b. Develop and provide a product label and marketing materials that accurately describes the risks of and does not overstate the benefits of using Invokana;

c. Provide full, complete, and accurate information to the FDA about Invokana;

d. Adequately test and study Invokana;

e. Ensure that the benefits of Invokana outweighed the risks for people susceptible to diabetic ketoacidosis, kidney failure of other adverse effects;

f. Conduct adequate post-market surveillance; and

g. Use a safer alternative formulation.

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

74. The design defect was such that the risks of Invokana outweighed its utility.

75. There were practical and technically feasible alternative designs that would not have reduced the utility of Invokana and would not have cost substantially more to develop, including, but not limited to providing a better warning with Invokana, using an alternative diabetes treatment, or developing an SLGT2 inhibitor with a different safety profile.

76. Defendants' defective design of Invokana was reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over

the safety and well-being of the consumers of Invokana.

76. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

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

78. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known of the design defects.

79. Plaintiff and Plaintiff's physicians did not have the same knowledge or expertise as Defendants and could not have discovered any defect in Invokana through the exercise of reasonable care.

80. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injury.

81. The defects in Invokana were substantial contributing factors in causing Plaintiff's injuries.

Count Two- Failure to Warn (Strict Liability)

82. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

83. The Defendants are liable under the theory of product liability as set forth in §402A and 402B of the Restatement of TORTS 2d and Restatement, Third, of Torts.

84. Defendants designed, developed researched, tested, licenses, manufactured,

packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Plaintiff. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

85. Invokana's inadequate warning rendered Invokana unreasonably dangerous and defective.

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

87. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

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

89. Plaintiff could not have discovered the unwarned of risks of using Invokana through the exercise of reasonable care.

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

91. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians. The warnings that were given by the Defendants were not accurate and were incomplete.

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

93. 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.

94. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug and failure to warn Plaintiff and her physicians about the significant risks inherent in Invokana therapy, Plaintiff sustained severe injury.

Count Three- Negligence

95. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

96. At all times relevant, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research,

distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Invokana.

97. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Invokana to cause or increase the harm of diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life threatening complications of those conditions.

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

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

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

101. As a result of the Defendants' aggressive marketing campaigns promoting off-label uses, including for type 1 diabetes, weight loss, and to improve blood pressure and kidney function, Defendants knew or should have known and expected that consumers would use Invokana for such off-label uses.

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

103. Plaintiff did not know the nature and extent of the injuries that could result from Invokana and were misinformed about the benefits of Invokana and could not have discovered the information independently.

104. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling Invokana, and failing to adequately test and warn of the risks and dangers of Invokana.

105. Despite the fact that Defendants knew of should have known that Invokana caused unreasonable, dangerous side effects, Defendants continued to market Invokana to consumers including Plaintiff, when there were safer alternative methods available.

106. Defendants' negligence was a foreseeable and proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Four- Gross Negligence

107. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

108. Defendants had a duty to provide adequate warnings and accurately describe the risks and benefits of taking Invokana.

109. Defendants breached that duty.

110. 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.

111. 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.

112. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious and deliberate 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 her healthcare providers.

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

114. 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.

115. 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.

116. 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 diabetes.

117. Plaintiff reasonably relied on Defendants' representations and suffered injuries as a

proximate result of that reliance.

118. 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.

Count Five- Breach of Implied Warranty

119. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

120. Prior to the time that the aforementioned product was used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's physicians and health care providers that Invokana was of merchantable quality and safe and fit for the use for which it was intended.

121. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including Invokana, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants when using Invokana. As a result, the Plaintiff used Defendants' product as it was warranted and as intended.

122. Invokana was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Invokana has dangerous propensities when used as intended and will cause severe injuries and damages as alleged herein.

123. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Six- Breach of Express Warranty

124. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

125. At all relevant times, Defendants expressly represented and warranted to Plaintiff and Plaintiff's physicians and health care providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing , and other written materials intended for physicians, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained, adequate warnings, and was efficacious.

126. In particular, the "Warnings and Precautions" section of the Invokana prescribing information purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about.

127. In particular the Consumer Medication Guide expressly indicated "What is the most important information I should know about Invokana?" and" What are the possible side effects of Invokana?" and "General information about the safe and effective use of INVOKANA" and fails to mention that Invokana has been associated with diabetic Ketoacidosis, kidney failure, or cardiovascular adverse events.

128. Plaintiff's physician prescribed Invokana and Plaintiff consumed Invokana reasonably replying upon these warranties. Plaintiff and Plaintiff's physicians did not know and could not have learned independently that Defendants' representations were false and misleading.

129. Defendants knew and expected, or should have known and expected, and intended Plaintiff to reply on their warranties.

130. The representations contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain

creating an express warranty that the goods shall conform to the affirmations of fact or promises.

131. In utilizing Invokana, Plaintiff reasonably relied on the skill, judgment, representations and foregoing warranties of Defendants.

131. These warranties and representations were false in that Invokana is not safe, effective, fit and property for its intended use because of its propensity to cause, among other conditions, diabetic ketoacidosis, kidney failure, and cardiovascular problems.

132. Because Invokana did not conform to the Defendants' express representation, Defendants breached said warranties.

133. As a foreseeable, direct, and proximate result of the breach of express warranties by Defendants breached the warranties.

Count Seven- Fraudulent Misrepresentation

134. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

135. Defendants intentionally and fraudulently misrepresented the safety and efficacy of Invokana in the product label and through its marketing activities.

136. In Particular, Defendants intentionally and fraudulently:

a. Failed to adequately warn about the risk of diabetic ketoacidosis;

b. Failed to provide full and complete information about Invokana to the FDA;

c. Provided a product label to Plaintiffs physicians that did not adequately disclose the risks that Defendants knew of;

d. Provided consumer information that did not adequately disclose the risks that Defendants knew of;

e. Overstated the benefits of Invokana; and

f. Marketed Invokana for unapproved uses such as weight loss and lowering blood pressure.

137. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them, in willful, wanton, and reckless disregard for the lack of truthfulness of the representations and with the intent to defraud and deceive Plaintiff and Plaintiff's physicians.

138. Plaintiff and Plaintiff's physicians reasonably relied on the fraudulent misrepresentations both as communicated to them directly from Defendants and as communicated to them by others exposed to Defendants' pervasive marketing campaigns.

Count Eight- Negligent Misrepresentation

139. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

140. From the time Invokana was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and health care providers, and the general public, including but not limited to the misrepresentation that Invokana was safe, fit, and effective for human consumption.

141. Defendants owed a duty to Plaintiff to exercise reasonable care to

ensure they did not misrepresent the safety or efficacy of Invokana nor create unreasonable risks of injury to others, and failed to exercise that reasonable care and therefore breached their duty.

142. The Defendants made the foregoing misrepresentations without any reasonable grounds for believing them to be true, and were in fact, reckless.

143. The Defendants had a duty to correct these material misstatements because they knew or should have known that they were inaccurate and that others would reasonably rely on them and suffer injury.

144. These misrepresentations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

145. The representations by the Defendants were in fact false, in that Invokana is not safe, fit and effective for human consumption, using Invokana is hazardous to health, and Invokana has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by plaintiff.

146. The foregoing representations by Defendants were made with the expectation and intention of inducing reliance upon them and increasing the prescription, purchase and use of Invokana.

147. Plaintiff reasonably relied on the misrepresentations made by the Defendants to their detriment.

148. In reliance of the misrepresentations by the Defendants, and each of

them, Plaintiff was induced to purchase and use Invokana.

149. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Invokana.

150. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

151. As a direct, proximate, and foreseeable result of Defendants' negligent misrepresentations, Plaintiff suffered injuries and damages as alleged herein.

Count Nine- Fraudulent Concealment

152. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

153. At all relevant times, Defendants knew that Invokana was defective, unreasonably unsafe, and that its risks were understated and its benefits were overstated.

154. Defendants willfully, intentionally and fraudulently concealed their knowledge from Plaintiff, Plaintiff's physicians, and the public, and instead knowingly provided false information.

155. Defendants withheld information that they had a duty to disclose through Invokana's labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Invokana was safe and effective.

156. Defendants withheld information about the severity of the

substantial risks of using Invokana and their knowledge of the safety signals regarding adverse effects of Invokana.

157. Defendants withheld information that Invokana was not safer or more effective than alternative diabetes medications available on the market.

158. The above facts were material and would have been considered important to a reasonable person.

159. Had the above facts been disclosed, they would have changed Plaintiff's decision to take Invokana and Plaintiff's physician's decision to provide samples of it or prescribe it.

160. Defendants had a duty to disclose the information to Plaintiff and Plaintiff's physicians.

161. Defendants had sole access to material facts concerning, and unique and special knowledge and expertise regarding, the dangers and unreasonable risks associated with ingesting Invokana.

162. Defendants knew or should have known and expected or should have expected and intended that Plaintiff and Plaintiff's physicians rely on the inaccurate information they provided.

163. As a foreseeable, direct, and proximate result of Defendants' actions and fraudulent concealment, Plaintiff suffered injury.

Count Ten- Fraud

164. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

165. Defendants' intentional misrepresentations and concealments

constitute fraud under state law and were made with the intent to defraud physicians and consumers, including Plaintiff and Plaintiff's physicians.

166. Specifically Defendants intentionally and fraudulently did the following:

a. Provided a "Warnings and Precautions" section of the Invokana prescribing information that purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about, but in which material and relevant information was fraudulently withheld from the section;

b. Provided Consumer Medication Guide that expressly indicated "What is the most important information I should know about Invokana?' and "What are the possible side effects of Invokana?" and "General information about the safe and effective use of Invokana" and fraudulently omits information Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events;

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

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

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

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

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

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

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

j. Affirmatively asserted that Invokana was safe and effective.

167. The number and extent of fraudulent marketing communications are too numerous to list and are so pervasive that they fraudulently influence healthcare providers and consumers even without direct exposure to the marketing information because, as intended by Defendants, others hear the fraudulent communications and come to believe them and communicate to others that Invokana is safe and effective.

168. Plaintiff and Plaintiff's healthcare providers were exposed to the product label and medication guide and the fraudulently inaccurate information described above.

169. Defendants had access to these facts, while Plaintiff and Plaintiff's physicians did not and were unaware of them and could not reasonably learn of them from and alternative source.

170. The above facts were material to Plaintiff and Plaintiff's physician's decision to use and give samples of Invokana, and they reasonably relied on

Defendants' representations.

171. As a direct, proximate, and foreseeable result of Defendants' fraud they caused Plaintiff injuries.

Punitive Damages Allegations

172. Plaintiff incorporates by reference each and every paragraph of the Complaint as if fully copied and set forth at length herein.

173. The acts, conduct and omissions of Defendants, as alleged throughout the Complaint were willful and malicious. Defendants committed these acts with a conscious 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 of Defendants.

174. Prior to the manufacturing, sale, and distribution of Invokana, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff: and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or

death from using Invokana.

175. 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 warn the public, including Plaintiff of the extreme risk of injury occasioned by said defects inherent in Invokana. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Invokana knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

176. Defendants' conduct was so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff and other consumers, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate Plaintiff for the injuries Plaintiff has and will suffer. Plaintiff further demands judgment against each of the Defendants for punitive damages. Plaintiff further demands payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiff further demands payment by each Defendant jointly and severally of pre and post judgment interest on the above and such other relief as the Court deems just.

NAPOLI SHKOLNIK LLC

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