IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
SAVANNAH DIVISION

RUSSELL MULLIS and LYNN BURKHALTER, **Plaintiffs,** **v.** **JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON CO.,** **Defendants.**	**Case No.** CV420-130 **COMPLAINT AND DEMAND FOR JURY TRIAL**

This is a products liability claim involving a diabetes medication that causes an unreasonable and dangerous risk of genital gangrene in consumers, which ultimately causes some consumers to undergo painful, expensive and permanent surgical procedures to repair their genitals and/or perineum.

JURISDICTION AND VENUE

1. Plaintiff Russell Mullis is and at all times relevant was a citizen and resident of Lyons, Georgia, which is part of the Southern District of Georgia, U.S. District Court.

2. Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson, Inc. Co. both have their principal places of business in New Jersey. Defendants sold the drug Invokana to Plaintiff, without warning that it would place him at a greatly increased risk of being diagnosed with Fournier's Gangrene, a flesh-eating disease of the genitals that caused him to suffer an open wound known as an abscess that required surgical treatment and debridement to repair.

3. Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson, Inc. Co. were both involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of Invokana, which reached consumers and medical providers in the

Southern District of Georgia, including Plaintiff.

4. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), because there is complete diversity between Plaintiff and Defendants, and the amount in controversy exceeds $75,000. The amount in controversy requirement is satisfied because Plaintiff has undergone extensive and complicated surgical procedures to treat his drug-induced injuries, and he claims additional amounts in pain and suffering.

5. A substantial part of the events and omissions giving rise to Plaintiff's causes of action, including his ingestion of Invokana and resulting medical treatment, occurred in the Southern District of Georgia. Pursuant to 28 U.S.C. § 1391(b)(2), venue is proper in the Southern District of Georgia, U.S. District Court.

NATURE OF THE CASE

3. This is an action for damages suffered by Russell Mullis 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 sale of Invokana, or canagliflozin, for the treatment of Type 2 diabetes.

4. Defendants Johnson & Johnson, Co. and Janssen Pharmaceuticals ("Janssen"), concealed their knowledge of Invokana's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community until at least October 2018, when the drug's label was changed to reflect the risk of Fournier's Gangrene.

5. 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 Fournier's Gangrene, also known as necrotizing fasciitis of the perineum. Other product liability claims involving Invokana have been consolidated in New Jersey federal court as part of MDL 2750, *In Re: Invokana (Canagliflozin) Products Liability*

Litigation, but Plaintiff's claim is not suitable for the MDL. The nature of Plaintiff's claimed injuries falls outside the scope of the MDL proceeding, and in fact were not even publicly known until August 2018 when government authorities published warnings about Fournier's Gangrene and diabetes medications, as described in more detail below.

6. After beginning treatment with Invokana, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff suffered a scrotal abscess due to Fournier's gangrene. Plaintiff's ingestion of the defective and unreasonably dangerous drug Invokana has caused and will continue to cause injury and damage to Plaintiff.

7. 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.

8. Plaintiff, Russell Mullis, began taking Invokana in 2015 and continued taking Invokana until late 2018.

9. As a result of using Defendants' Invokana, Plaintiff was required to have seven surgeries of his scrotal area including incision and drainage, multiple debridements, and placement of wound vac in August 2019 at Doctor's Hospital: Burn Center in Augusta, Georgia following a diagnosis of Fournier's Gangrene.

10. The U.S. Food and Drug Administration ("FDA") on August 29, 2018, issued a warning about the link between Fournier's gangrene and certain Type 2 diabetes drugs, including SGLT2 inhibitors such as Invokana.[1] Defendants' label for Invokana did not contain a warning for Fournier's gangrene at the time, and it was not changed until at least October 2018.

[1] FDA Warns About Rare Occurences of a Serious Infection of the Genital Area with SGLT2 Inhibitors for Diabetes, available at https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm. This guidance updated an earlier statement made by the FDA in late 2017 that the agency was investigating the same issue with drugs, including both Invokana and Invokamet. The earlier statement did not contain a warning, but was merely advisory in nature. See https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm605800.htm

11. The label previously stated only that gangrene may be a complication associated with lower limb amputations. It also stated that animal studies were not conducted for Invokana, but that in animal studies of canagliflozin and metformin individually, there were incidents of testicular tumors. Nowhere did the label state that a male patient might suffer Fournier's gangrene, or lose part of his scrotum. Thus, Plaintiff had no way of knowing that his Fournier's gangrene could have been caused by his ingestion of Invokana, until he learned about the FDA warning a few months ago. His statute of limitations was therefore tolled until the FDA's announcement, at the earliest.

12. As a result of using Defendants' Invokana, Plaintiff was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress, including seven surgical procedures, constant scrotal/testicular pain, scarring, and fibrosis of scrotal area.

13. The injuries and damages sustained by Plaintiff were caused by Defendants' Invokana.

PARTY DEFENDANTS

14. Johnson & Johnson Co. is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson 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.

15. Defendant Janssen is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson. Janssen 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.

FACTUAL BACKGROUND

16. Defendant Johnson & Johnson was involved in the design and development of the Type 2 diabetes drug Invokana.

17. 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 Georgia.

18. Invokana is one of Defendants' top selling drugs, with sales of $215 million in just the second quarter of 2018.

19. In 2013, the FDA approved Invokana (canagliflozin) for the treatment of type 2 diabetes. The drug's label did not convey adequate warnings about genital gangrene, even though Defendants knew or should have known of these risks. The FDA issued a warning about the increased risk of Fournier's Gangrene on August 29, 2018, stating, in part, as follows:

> The U.S. Food and Drug Administration (FDA) is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

The FDA further stated that from March 2013 to May 2018, the agency identified 12 cases of Fournier's gangrene in patients taking an SGLT2 inhibitor such as Invokana or Invokamet. All 12 patients were hospitalized and required surgery. By comparison, only 6 cases of Fournier's gangrene were identified by the FDA in a review of other antidiabetic drugs over a period of 30 years.

20. *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. When combined with metformin, it is sold as Invokamet.

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

22. 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.

23. Though Invokana is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market Invokana for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

24. Since Invokana's release, the FDA has received a significant number of reports of Fournier's gangrene among users of Invokana, in addition to reports about other unrelated injuries.

25. An analysis of the FDA's adverse event database, in combination with the FDA's own research, shows that patients taking Invokana are more likely to report Fournier's gangrene than those taking non-SGLT2 diabetes drugs to treat diabetes. More than 10,000 serious adverse events involving Invokana have been reported to the FDA since the drug's approval in 2013, including 4,900 infections. The agency's Adverse Events Reporting System, or FAERS, shows dozens of incidents of "diabetic gangrene" beginning as early as 2013, the year Invokana was first approved.[2]

[2] See FAERS database, https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last visited Jan. 29, 2018).

26. Despite Defendants' knowledge of the increased risk of Fournier's gangrene among Invokana users, Defendants did not warn patients but instead continued to promote and distribute Invokana, mislead physicians and the public, and minimize unfavorable findings.

27. Consumers, including Plaintiff, who have used Invokana for treatment of diabetes, have several alternative safer products available to treat the conditions, which do not cause Fournier's gangrene.

28. Defendants knew of the significant risk of Fournier's gangrene 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.

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

30. As a direct result, in or about 2015, Plaintiff was prescribed and began taking Invokana, primarily to treat his Type 2 diabetes.

31. Plaintiff ingested and used Invokana as prescribed by his physicians in Georgia and in a foreseeable manner.

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

33. Plaintiff agreed to initiate treatment with Invokana in an effort to reduce his blood sugar. In doing so, Plaintiff relied on claims made by Defendants that Invokana was safe and effective for the treatment of Type 2 diabetes.

34. Instead, Invokana can cause severe injuries, including Fournier's gangrene.

35. After beginning treatment with Invokana, and as a direct and proximate result thereof, Plaintiff suffered Fournier's gangrene, which resulted in the complex incision and drainage and debridement of the scrotum and placement of a wound vac to wound site in August 2019, at Doctor's Hospital: Burn Center by Dr. Robert Mullins.

36. Defendants knew or should have known the risks associated with the use of Invokana, including the risk of Fournier's gangrene.

37. 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, was a substantial factor in bringing about and exacerbating Plaintiff's injuries.

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

39. 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.

40. 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.

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

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

43. 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, loss of intimacy with his spouse, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff Lynn Burkhalter has suffered a loss of consortium as a direct and proximate result of Defendants' conduct. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

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

FIRST CAUSE OF ACTION
(NEGLIGENCE)

45. Plaintiff repeats, reiterates and realleges 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.

46. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Invokana into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

47. Defendants failed to exercise ordinary care 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 a high risk of unreasonable, dangerous side effects, including Fournier's gangrene, 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.

48. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Invokana without thoroughly testing it for Fournier's gangrene and other injuries to the testicles, perineum and scrotum;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Invokana without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Invokana was safe for use; in that Defendants herein knew or should have known that Invokana was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Invokana without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Invokana;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Invokana;

(g) Failing to test Invokana and/or failing to adequately, sufficiently and properly test Invokana.

(h) Negligently advertising and recommending the use of Invokana without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Invokana was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Invokana had equivalent safety and efficacy as other forms of treatment for diabetes;

(k) Negligently designing Invokana in a manner which was dangerous to its users;

(l) Negligently manufacturing Invokana in a manner which was dangerous to its users;

(m) Negligently producing Invokana in a manner which was dangerous to its users;

(n) Negligently assembling Invokana in a manner which was dangerous to its users;

(o) Concealing information from the Plaintiff in knowing that Invokana was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Invokana compared to other forms of treatment for diabetes.

49. Defendants under-reported, underestimated and downplayed the serious dangers of Invokana.

50. Defendants negligently compared the safety risk and/or dangers of Invokana with other forms of treatment for diabetes.

51. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Invokana in that they:

(a) Failed to use due care in designing and manufacturing Invokana so as to avoid the aforementioned risks to individuals when Invokana was used for treatment for diabetes;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Invokana;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects, including but not limited to Fournier's gangrene, concerning the failure and/or malfunction of Invokana;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Invokana;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Invokana;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of Invokana, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

52. Despite the fact that Defendants knew or should have known that Invokana and Invokana caused unreasonably dangerous side effects, including but not limited to Fournier's gangrene, Defendants continued and continue to market, manufacture, distribute and/or sell the drugs to consumers, including the Plaintiff.

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

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

55. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including Fournier's gangrene, 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.

56. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

57. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of $75,000.00.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

58. Plaintiff repeats, reiterates and realleges 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.

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

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

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

62. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when

it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Invokana.

63. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

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

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

66. At the time of the Plaintiff's use of Invokana, the drug was being used for the purposes and in a manner normally intended, namely to control high blood sugar in people with type 2 diabetes.

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

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

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

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

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

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

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

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

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

76. The Invokana designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, Fournier's gangrene, as well as other severe and permanent health consequences from Invokana, they failed to provide adequate warnings to users or consumers of

the product, and continued to improperly advertise, market and/or promote their product, Invokana.

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

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

79. That said defects in Defendants' drug Invokana were a substantial factor in causing Plaintiff's injuries.

80. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including Fournier's gangrene, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, and including diminished enjoyment of life.

81. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

82. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount to be determined at trial by jury, but easily exceeding $75,000.00 including medical expenses past and future, and pain and suffering past and future.

THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

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

84. 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.

85. 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.

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

87. 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.

88. 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 his health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of Invokana, but those risks are neither accurately nor adequately set forth, including the specific risk of Fournier's gangrene.

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

90. 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.

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

92. Neither Plaintiff nor his prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning Invokana.

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

94. Had the prescribing information for Invokana accurately and adequately set forth the true risks associated with the use of such product, including Plaintiff's genital 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.

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

96. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

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

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

99. 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.

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

101. 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 Fournier's gangrene or diabetic gangrene.

102. 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 for Fournier's gangrene and/or necrotizing fasciitis.

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

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

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

106. 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.

107. 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.

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

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

110. 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.

111. 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.

112. 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.

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

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

115. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered Fournier's gangrene, a scrotal abscess, seven surgeries of his scrotal area including incision and drainage and multiple debridements with placement of wound vac, wound scarring and fibrosis, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

118. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

116. Plaintiff repeats, reiterates and realleges 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.

117. 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.
(c) 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.

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

119. 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.

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

121. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered Fournier's gangrene and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services.

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

122. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

SIXTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

123. Plaintiff repeats, reiterates and realleges 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.

124. 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.

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

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Invokana was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using Invokana; and
(b) Upon information and belief, Defendants represented that Invokana was safer than other alternative medications and fraudulently concealed information which demonstrated that Invokana was not safer than alternatives available on the market.
(c) Defendants were under a duty to Plaintiff, to disclose and warn of the defective and dangerous nature of Invokana because:
(d) Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of Invokana;

(e) 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
(f) Defendants fraudulently and affirmatively concealed the defective and dangerous nature of Invokana from Plaintiff.

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

127. 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.

128. 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.

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

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

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

132. Defendants, by concealment or other action, intentionally prevented Plaintiff and him 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.

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

134. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

SEVENTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

135. Plaintiff repeats, reiterates and realleges 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.

136. 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.

137. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of Invokana with the intention that health care professionals and consumers

would rely upon that information in their decisions concerning whether to prescribe or ingest Invokana.

138. 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.

139. 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.

140. 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.

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

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

(b) concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of Invokana, when compared to comparable or superior alternative drug therapies; and
(c) misrepresenting Invokana's risk of unreasonable, dangerous, adverse side effects.

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

143. 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.

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

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

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

147. 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.

148. 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.

149. 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.

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

151. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

EIGHTH CAUSE OF ACTION
(FRAUD AND DECEIT)

152. Plaintiff repeats, reiterates and realleges 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.

153. Defendants conducted research and used Invokana as part of their research.

154. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Invokana was safe and effective for use as a means to control high blood sugar in people with type 2 diabetes.

155. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff, as it relates to Fournier's gangrene, and/or diabetic gangrene, the risks of which were well known even in 2013 when Invokana was approved, based on early adverse events involving these injuries.

156. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA about the risks of Fournier's gangrene.

157. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

158. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Invokana was safe and effective for use to control high blood sugar in people with type 2 diabetes, and by omitting any mention of the risk of Fournier's gangrene.

159. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Invokana carried the same risks,

hazards, and/or dangers as other forms of treatment control high blood sugar in people with type 2 diabetes.

160. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Invokana was not injurious to the health and/or safety of its intended users, and that it would not cause an increased risk of Fournier's gangrene.

161. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Invokana was as potentially injurious to the health and/or safety of its intended as other forms of treatment to control high blood sugar in people with type 2 diabetes.

162. These representations and/or omissions were all false and misleading.

163. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results and adverse events that were not favorable to the Defendants, and results that demonstrated that Invokana was not safe as a means of treatment for controlling high blood sugar in people with type 2 diabetes, and that Invokana would cause an increased risk of Fournier's gangrene in consumers.

164. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Invokana, specifically but not limited to Invokana not having dangerous and serious health and/or safety concerns related to Fournier's gangrene.

165. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Invokana, specifically but not limited to Invokana being a safe means of controlling high blood sugar in people with type 2 diabetes.

166. It was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Invokana and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Invokana.

167. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Invokana was fit and safe for use as treatment to control high blood sugar in people with type 2 diabetes.

168. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Invokana was fit and safe for use as treatment for controlling high blood sugar in people with type 2 diabetes.

169. Defendants made claims and representations in documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Invokana did not present serious health and/or safety risks including Fournier's gangrene.

170. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff that Invokana did not present health and/or safety risks related to Fournier's gangrene that were greater than other forms of treatment for controlling high blood sugar in people with type 2 diabetes.

171. These representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

172. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including his respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or his respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Invokana.

173. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Invokana to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for controlling high blood sugar in people with type 2 diabetes.

174. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Invokana by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Invokana. Defendants had the opportunity to change the drug's label based on information in their possession about the risks of Fournier's gangrene, but they withheld this information from the public and from regulatory agencies, and did not take action to change the label to add warnings about Fournier's gangrene until on or about October 2018, and only then because they were forced to do so by FDA regulators.

175. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as his respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Invokana and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

176. Defendants, through their public relations efforts, which included but were not limited to public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

177. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Invokana.

178. That the Plaintiff and/or his respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for controlling high blood sugar in people with type 2 diabetes.

179. At the time the representations were made, Plaintiff and/or his respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Invokana, related to Fournier's gangrene.

180. Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts, until at the very least August 2018.

181. Had Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Invokana, Plaintiff would not have purchased, used and/or relied on Defendants' drug Invokana.

182. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

183. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including Fournier's gangrene, 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.

184. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

185. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount exceeding $75,000.00.

NINTH CAUSE OF ACTION
(GEORGIA PRODUCTS LIABILITY ACT
(O.C.G.A. § 51-1-11 *et seq*))

186. Plaintiff repeats, reiterates and realleges 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.

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

188. 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.

189. 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.

190. 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 than 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 injuries from Fournier's gangrene;
(f) Inadequate post-marketing surveillance; and/or
(g) There were safer alternative designs and formulations that were not utilized.

191. 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.

192. 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.

193. 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 than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

194. 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 the manner instructed, provided, and/or promoted by Defendants.

195. 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.

196. 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.

197. 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.

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

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

200. 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.

201. 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.

202. 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.

203. Due to the unreasonably dangerous condition of Invokana, Defendants are liable to Plaintiff pursuant to the Georgia Products Liability Act, O.C.G.A. § 51-1-11. Plaintiff, as a purchaser of Invokana, is within the class of persons the statutes and regulations are designed to protect and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

204. 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.

205. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered Fournier's gangrene 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.

206. 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.

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

TENTH CAUSE OF ACTION
PRODUCTS LIABILITY – FAILURE TO WARN

208. Plaintiff repeats, reiterates and realleges 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.

209. 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.

210. 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 including Fournier's gangrene.

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

212. Invokana, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions, which were not changed to reflect the risk of Fournier's gangrene until October 2018, and only then because FDA regulators ordered that the warning be changed.

213. 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.

214. Invokana was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff.

215. 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 from Fournier's gangrene.

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

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

218. Defendants negligently and recklessly labeled, distributed, and promoted Invokana.

219. Defendants had a continuing duty to warn Plaintiff of the dangers of Fournier's gangrene associated with Invokana, which they either knew or should have known about based in part on adverse events reported to the FDA as early as 2013 for similar injuries.

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

221. 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.

222. 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 including Fournier's gangrene and necrotizing fasciitis to the genitals and perineum. 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.

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

224. 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.

225. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

(a) disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Invokana;
(b) continued to aggressively promote Invokana even after Defendants knew or should have known of the unreasonable risks from use;
(c) failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Invokana and the comparative severity of such adverse effects;
(d) failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Invokana's capacity to cause its users to suffer Fournier's gangrene;
(e) failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients who do not already suffer from renal impairment; and
(f) overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Invokana.

226. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Invokana, notwithstanding the recent label change in October 2018.

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

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

229. 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.

230. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered Fournier's gangrene and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished

quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

ELEVENTH CAUSE OF ACTION
(PRODUCT LIABILITY – MANUFACTURING DEFECT

231. Plaintiff repeats, reiterates and realleges 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.

232. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Invokana.

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

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

(a) When placed in the stream of commerce, Invokana contained manufacturing defects which rendered the product unreasonably dangerous;
(b) The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;
(c) The subject product was not made in accordance with Defendants' specifications or performance standards; and/or
(d) The subject product's manufacturing defects existed before it left the control of Defendants.

235. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

TWELFTH CAUSE OF ACTION
(PUNITIVE DAMAGES)

236. Plaintiff repeats, reiterates and realleges 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.

237. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Invokana, including risk of Fournier's gangrene and necrotizing fasciitis to the genitals and perineum.

238. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Invokana, despite available information that Invokana was likely to cause serious side effects and/or complications.

239. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Invokana, despite available information that Invokana was likely to cause serious side effects and/or complications.

240. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

241. Defendants were or should have been in possession of evidence demonstrating that Invokana causes serious side effects. Nevertheless, Defendants continued to market Invokana by providing false and misleading information with regard to safety and efficacy.

242. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing Invokana to consumers, from purchasing and consuming Invokana, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Invokana.

THIRTEENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)

243. Plaintiffs incorporate herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

244. As a direct and proximate result of the above described injuries sustained by Plaintiff Russell Mullis, his wife, Plaintiff Lynn Burkhalter, has suffered a loss of her husband's consortium, companionship, society, affection, services and support.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless

acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

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

Dated: June 10, 2020.

Respectfully Submitted,

TATE LAW GROUP, LLC

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