UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION

LEE LETOURNEAU

Plaintiff,

COMPLAINT AND DEMAND FOR JURY TRIAL

vs.

JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON CO.,

Defendants.

MDL NO. 2750
Master Docket No. 3:16-md-2750

JUDGE BRIAN R. MARTINOTTI
JUDGE LOIS H. GOODMAN

DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4

Civil Action No.: 1:18-cv-13584

Plaintiff, Lee Letourneau, for his Invokamet Fourier's Gangrene Injury Complaint against Defendants, alleges as follows:

JURISDICTION AND VENUE

1. Plaintiff files this Invokamet Fournier's Gangrene Injury Complaint pursuant to CMO No. 4, and is to be bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiff hereby designates the United States District Court for the District of Connecticut as the place of remand as this case may have originally been filed there.

2. Defendants have their principal places of business in New Jersey rather than the state in which the named Plaintiff resides. Defendants sold the drug INVOKAMET to Plaintiff, without

warning that it would result in him being diagnosed with Fournier's gangrene, a flesh-eating disease of the genitals that caused him to have more than half of his scrotum surgically removed.

NATURE OF THE CASE

3. This is an action for damages suffered by Lee Letourneau 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 for the treatment of diabetes.

4. Defendants Johnson & Johnson, Co. ("JOHNSON & JOHNSON"), and Janssen Pharmaceuticals ("JANSSEN"), concealed, and continue to conceal, their knowledge of INVOKANA and INVOKAMET's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community. INVOKAMET contains both canagliflozen, or INVOKANA, and also metformin hydrochloride, or Glucophage.

5. As a result of the defective nature of INVOKAMET, persons who were prescribed and ingested INVOKAMET, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including amputation, diabetic ketoacidosis, kidney damage, and Fournier's gangrene, also known as necrotizing fasciitis of the perineum.

6. After beginning treatment with INVOKAMET, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff suffered a partial removal of his scrotum due to Fournier's gangrene. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKAMET 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 INVOKAMET. Plaintiff accordingly seeks compensatory and punitive

damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKAMET.

PARTY PLAINTIFF

8. Plaintiff, Lee Letourneau is a citizen and resident of the State of Connecticut, living in West Haven, West Haven County, at all relevant times.

9. Plaintiff, Lee Letourneau, was born Oct. 14, 1971.

10. Plaintiff, Lee Letourneau, began taking INVOKAMET in February 2017 and continued taking INVOKAMET until late 2017.

11. As a result of using Defendants' INVOKAMET, Plaintiff was caused to suffer the surgical removal of approximately 60% of his scrotum following a diagnosis of Fournier's gangrene. The U.S. Food and Drug Administration 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 INVOKAMET does not contain a warning for Fournier's gangrene. The label states only that gangrene may be a complication associated with lower limb amputations. It also states that animal studies were not conducted for INVOKAMET, but that in animal studies of canagliflozin and metformin individually, there were incidents of testicular tumors. Nowhere does the label state that a male patient might suffer Fournier's gangrene, or lose part of his scrotum.[2]

[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

[2] Invokamet Label, available at http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVOKAMET-pi.pdf.

12. As a result of using Defendants' INVOKAMET, Plaintiff was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress, including surgical removal of his scrotum.

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

PARTY DEFENDANTS

14. JOHNSON & JOHNSON 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 INVOKAMET.

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 INVOKAMET.

FACTUAL BACKGROUND

16. Defendant JOHNSON & JOHNSON was involved in the design and development of the diabetes drug, INVOKAMET.

17. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, acquired the marketing rights to INVOKAMET in North America, and marketed, advertised,

distributed, and sold INVOKAMET in the United States, including in the State of New Jersey and the State of Connecticut.

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

19. In 2014, the United States Food and Drug Administration ("FDA") approved Defendants' compound INVOKAMET (*canagliflozin*) for the treatment of type 2 diabetes. The drug's label did not convey adequate warnings about amputation. 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 Mary 2018, the agency identified 12 cases of Fournier's gangrene in patients taking an SGLT2 inhibitor such as 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 INVOKAMET, 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 and INVOKAMET, 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 INVOKAMET 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 severe kidney damage among users of INVOKANA, in addition to the above-referenced reports about Fournier's gangrene.

25. An analysis of the FDA's adverse event database, in combination with the FDA's own research, shows that patients taking INVOKAMET are more likely to report Fournier's gangrene than those taking non-SGLT2 diabetes drugs to treat diabetes.

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

27. Consumers, including Plaintiff, who have used INVOKANA and INVOKAMET 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 INVOKAMET. 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 INVOKAMET 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 INVOKAMET.

30. As a direct result, in or about February 2017, Plaintiff was prescribed and began taking INVOKAMET, primarily to treat his Type 2 diabetes.

31. Plaintiff ingested and used INVOKAMET as prescribed by his physician in Connecticut and in a foreseeable manner.

32. The INVOKAMET 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 INVOKAMET in an effort to reduce his blood sugar. In doing so, Plaintiff relied on claims made by Defendants that INVOKAMET was safe and effective for the treatment of diabetes.

34. Instead, INVOKAMET 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 emergency removal of part of his scrotum on November 26, 2017, at Stamford Hospital in Stamford, Connecticut by Dr. Michael Karellas.

36. Defendants knew or should have known the risks associated with the use of INVOKAMET, 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 INVOKAMET. 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 INVOKAMET'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 INVOKAMET without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

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

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

42. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that

Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

43. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKAMET, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

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 INVOKAMET.

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 INVOKAMET 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 INVOKAMET into interstate commerce in that Defendants knew or should have known that using INVOKAMET 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 INVOKAMET 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 INVOKAMET without adequately testing it;

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

(d) Selling INVOKAMET 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 INVOKAMET;

(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, INVOKAMET;

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

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

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

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

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

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

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

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

(o) Concealing information from the Plaintiff in knowing that INVOKAMET 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 INVOKAMET compared to other forms of treatment for diabetes.

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

50. Defendants negligently compared the safety risk and/or dangers of INVOKAMET 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 INVOKAMET in that they:

(a) Failed to use due care in designing and manufacturing INVOKAMET so as to avoid the aforementioned risks to individuals when INVOKAMET 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 INVOKAMET;

(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 INVOKAMET;

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

(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 INVOKAMET;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of INVOKAMET, 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 INVOKAMET 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 INVOKAMET as hereinabove described that was used by the Plaintiff.

60. That INVOKAMET 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, INVOKAMET was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

62. The INVOKAMET 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 INVOKAMET.

63. The INVOKAMET 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, INVOKAMET 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 INVOKAMET was in a defective condition, and was and is inherently dangerous and unsafe.

66. At the time of the Plaintiff's use of INVOKAMET, 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 INVOKAMET 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 INVOKAMET designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that INVOKAMET left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

71. The INVOKAMET 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' INVOKAMET 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 INVOKAMET's defects herein mentioned and perceived its danger.

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

76. The INVOKAMET 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 INVOKAMET, they failed to provide adequate warnings to users or consumers

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

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, INVOKAMET.

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

79. That said defects in Defendants' drug INVOKAMET 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 INVOKAMET, which is unreasonably dangerous and defective, thereby placing INVOKAMET 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 INVOKAMET:

(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 INVOKAMET. 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 INVOKAMET as safe and effective for use.

87. Defendants advertised, labeled, marketed, and promoted INVOKAMET, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce

INVOKAMET's purchase or use, thereby making an express warranty that INVOKAMET would conform to the representations. More specifically, the prescribing information for INVOKAMET 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 INVOKAMET 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 her health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of INVOKAMET, but those risks are neither accurately nor adequately set forth, including the specific risk of Fournier's gangrene.

89. The representations about INVOKAMET 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. INVOKAMET 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, INVOKAMET 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 her prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning INVOKAMET.

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

94. Had the prescribing information for INVOKAMET 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 INVOKAMET.

99. At all relevant times, Defendants knew of the use for which INVOKAMET 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 INVOKAMET 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. INVOKAMET was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKAMET has dangerous propensities when used as intended and can cause serious injuries, including stroke, heart attack, ketoacidosis, amputation and severe kidney damage.

102. At all relevant times, Defendants intended that INVOKAMET 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 INVOKAMET was not adequately tested for Fournier's gangrene and/or necrotizing fasciitis.

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

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

105. INVOKAMET 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 INVOKAMET 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. INVOKAMET 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 INVOKAMET.

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

110. INVOKAMET 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 INVOKAMET was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

112. The harm caused by INVOKAMET far outweighed its alleged benefit, rendering INVOKAMET 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 INVOKAMET.

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, loss 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.

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 INVOKAMET in the following particulars:

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

(b) Upon information and belief, Defendants represented that INVOKAMET 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 INVOKAMET 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 her 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 INVOKAMET.

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 INVOKAMET 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 INVOKAMET.

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

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKAMET was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using INVOKAMET; and

(b) Upon information and belief, Defendants represented that INVOKAMET was safer than other alternative medications and fraudulently concealed information which demonstrated that INVOKAMET 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 INVOKAMET because:

(d) Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of INVOKAMET;

(e) Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKAMET 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 INVOKAMET from Plaintiff.

126. As the designers, manufacturers, sellers, promoters, and/or distributors of INVOKAMET, Defendants had unique knowledge and special expertise regarding INVOKAMET. This placed them in a position of superiority and influence over Plaintiff and her healthcare providers. As such, Plaintiff and her 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 INVOKAMET.

128. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by INVOKAMET was intentional, and the representations made by Defendants were known by them to be false.

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

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

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

132. Defendants, by concealment or other action, intentionally prevented Plaintiff and her health care professionals from acquiring material information regarding the lack of safety of INVOKAMET, 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 INVOKAMET, 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 INVOKAMET with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest INVOKAMET.

138. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of INVOKAMET, knew or reasonably should have known that health care professionals and consumers of INVOKAMET rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting INVOKAMET.

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 INVOKAMET 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 INVOKAMET, knew or reasonably should have known that health care professionals would write prescriptions for INVOKAMET in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for INVOKAMET 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 INVOKAMET 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 INVOKAMET. Defendants made material misrepresentations to Plaintiff, her health care professionals, the healthcare community, and the general public, including:

(a) stating that INVOKAMET 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 INVOKAMET, when compared to comparable or superior alternative drug therapies; and

(c) misrepresenting INVOKAMET'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 INVOKAMET.

145. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that INVOKAMET 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 INVOKAMET and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of INVOKAMET.

148. Defendants engaged in a nationwide marketing campaign, over-promoting INVOKAMET 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 INVOKAMET while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of INVOKAMET, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented INVOKAMET'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 INVOKAMET, 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 INVOKAMET 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 INVOKAMET 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.

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.

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 INVOKAMET was safe and effective for use to control high blood sugar in people with type 2 diabetes.

159. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug INVOKAMET 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 INVOKAMET was not injurious to the health and/or safety of its intended users.

161. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that INVOKAMET 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 were all false and misleading.

163. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that INVOKAMET was not safe as a means of treatment for controlling high blood sugar in people with type 2 diabetes.

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

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 INVOKAMET, specifically but not limited to INVOKAMET being a safe means of controlling high blood sugar in people with type 2 diabetes.

166. That 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 INVOKAMET and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use INVOKAMET.

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 INVOKAMET 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

INVOKAMET was fit and safe for use as treatment for controlling high blood sugar in people with type 2 diabetes.

169. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that INVOKAMET did not present serious health and/or safety risks.

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

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

173. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of INVOKAMET 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 INVOKAMET 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.

175. That 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 INVOKAMET 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 INVOKAMET.

178. That the Plaintiff and/or her 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. That at the time the representations were made, the 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 INVOKAMET.

180. That the 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.

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

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
(VIOLATION OF THE NEW JERSEY

CONSUMER FRAUD ACT)

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. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise…" and declares such acts or practices as unlawful.

188. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of INVOKANA and INVOKAMET. Defendants communicated the purported benefits of INVOKAMET while failing to disclose the serious and dangerous side effects related to the use of INVOKAMET with the intent that consumers, including Plaintiff, and her healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe INVOKAMET, respectively.

189. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use INVOKAMET, causing severe injuries and damages as previously described herein.

TENTH CAUSE OF ACTION
(PRODUCT LIABILITY – DESIGN DEFECT—
(N.J.S.A. 2A:58C-1 *et seq*))

190. 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.

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

192. Defendants expected INVOKAMET 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.

193. At all times relevant hereto, Defendants' INVOKAMET 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.

194. At all times relevant to this action, INVOKAMET, 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, INVOKAMET 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, INVOKAMET 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) INVOKAMET was insufficiently tested;

(d) INVOKAMET caused harmful side effects that outweighed any potential utility;

(e) Defendants were aware at the time INVOKAMET was marketed that ingestion of INVOKAMET would result in an increased risk of diabetic ketoacidosis and other injuries including Fournier's gangrene;

(f) Inadequate post-marketing surveillance; and/or

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

195. INVOKAMET 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.

196. INVOKAMET, 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 INVOKAMET's design or formulation.

197. INVOKAMET, 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.

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

199. 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 INVOKAMET was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

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

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

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

203. The harm caused by INVOKAMET 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 INVOKAMET to make it less dangerous. When Defendants designed INVOKAMET, the state of the industry's scientific knowledge was such that a less risky design was attainable.

204. At the time INVOKAMET 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 INVOKAMET. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

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

206. The defects in INVOKAMET 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.

207. Due to the unreasonably dangerous condition of INVOKAMET, Defendants are liable to Plaintiff.

208. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKAMET, including Plaintiff, with knowledge of the safety problems associated with INVOKAMET, 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.

209. 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
PRODUCTS LIABILITY – FAILURE TO WARN
(N.J.S.A. 2A:58C-1 *et seq.*))

210. 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.

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

212. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released INVOKAMET into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted INVOKAMET 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 INVOKAMET including Fournier's gangrene.

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

214. INVOKAMET, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product

created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

215. INVOKAMET 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. INVOKAMET contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with INVOKAMET, including the development of Plaintiff's injuries.

216. This defect caused serious injury to Plaintiff, who used INVOKAMET 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 INVOKAMET did not cause users to suffer from unreasonable and dangerous risks.

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

219. Defendants had a continuing duty to warn Plaintiff of the dangers associated with INVOKAMET.

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 INVOKAMET 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 INVOKAMET 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 INVOKAMET, 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. INVOKAMET, 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 INVOKAMET 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 INVOKAMET;

(b) continued to aggressively promote INVOKAMET 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 INVOKAMET 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 INVOKAMET's capacity to cause its users to suffer diabetic ketoacidosis and 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 INVOKAMET.

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

227. Due to these deficiencies and inadequacies, INVOKAMET 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 INVOKAMET, Plaintiff would have avoided the risk of developing injuries as alleged herein.

229. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of INVOKAMET 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.

TWELFTH CAUSE OF ACTION
(PRODUCT LIABILITY – MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1 *et seq.*))

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 INVOKAMET.

233. At all times material to this action, INVOKAMET was expected to reach, and did reach, consumers in the State of Connecticut 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, INVOKAMET 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, INVOKAMET 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.

THIRTEENTH CAUSE OF ACTION
(PUNITIVE DAMAGES UNDER COMMON LAW,
THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 *et seq.*)
AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*))

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 INVOKAMET, 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 INVOKAMET, despite available information that INVOKAMET 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 INVOKAMET, despite available information that INVOKAMET 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 INVOKAMET causes serious side effects. Nevertheless, Defendant continued to market INVOKAMET 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 INVOKAMET to consumers, from purchasing and consuming INVOKAMET, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming INVOKAMET.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff 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: September 6, 2018

Respectfully Submitted,

JONES WARD PLC

/s/ Alex C. Davis
Alex C. Davis
Jasper D. Ward IV
The Pointe
1205 E. Washington St.
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Louisville, Kentucky 40206
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Fax (502) 587-2007
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jasper@jonesward.com
Counsel for Plaintiff

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Lee Letourneau

(b) County of Residence of First Listed Plaintiff New Haven (CT)
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alex C. Davis and Jasper D. Ward, The Pointe, 1205 E. Washington St., Suite 111, Louisville KY 40206. Tel. 502-882-6000.

DEFENDANTS
JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON CO.,

County of Residence of First Listed Defendant Middlesex (NJ)
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	FEDERAL TAX SUITS	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence		❒ 871 IRS—Third Party 26 USC 7609	❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332
Brief description of cause:
Invokamet products liability claim

VII. REQUESTED IN COMPLAINT:
❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.
DEMAND $ 75000
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*
JUDGE Hon. Brian R. Martinotti DOCKET NUMBER 3:16-md-2750

DATE
September 6, 2018

SIGNATURE OF ATTORNEY OF RECORD
s/ Alex C. Davis

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

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

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

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

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