UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	MDL No. 2750 Master Docket No. 3:16-md-2750
Bonnie Hamm, Plaintiff, vs. Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC, Defendants.	JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4 CIVIL ACTION NO.:_____

Plaintiff(s), Bonnie Hamm, files this 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 Northern District of Tennessee, as the place of remand as this case may have originally been filed there.

Plaintiff by and through the undersigned attorney, submit this complaint and jury demand against Defendants JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, JANSSEN ORTHO, LLC, and JANSSEN PHARMACEUTICALS, INC.

As more specifically set forth below, Plaintiff(s) maintain that the diabetes drug, INVOKANA/INVOKAMET, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warning to the dangers associated with its use. This case is being filed in accordance with Case Management Order No. 4 of the *In re: INVOKANA* MDL No. 2750.

NATURE OF ACTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA/INVOKAMET (at times referred to herein as "the subject product") for the treatment of diabetes.

2. Defendants are the manufacturers of the prescription drug INVOKANA/INVOKAMET, developed and indicated for the treatment of type 2 diabetes. It was initially approved by the FDA in January of 2014 and is in a class of new diabetes drugs called glucose cotransporter-2 ("SGLT-2") inhibitors. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. As the name suggests, SGLT-2 inhibitors decrease sugar in the bloodstream by inhibiting glucose reabsorption. The extra sugar is then eliminated from the body through urine produced by the user's kidneys, putting extra strain on the kidneys of patients that already have increased insult to their kidneys by virtue of having diabetes.

3. In May 2015, the FDA issued a safety communication warning that SGLT-2 inhibitors (including INVOKANA/INVOKAMET) can cause life-threatening diabetic ketoacidosis ("DKA"), having discovered more than 20 cases that had been reported to FDA's adverse event reporting system ("FAERS"). Although DKA in Type 1 diabetics occurs with some frequency, it is uncommon in Type 2 diabetics.

4. On May 16, 2017, the FDA issued a safety communication confirming that INVOKANA/INVOKAMET use increases the risk of leg and foot amputations, based on data from two large clinical trials. This led to the FDA requiring a black boxed warning to be added

to the label of INVOKANA, INVOKAMET, and INVOKAMET XR (the latter two being combination drugs of Invokana and metformin, another oral hypoglycemic) regarding the risk of amputation. The risk was not found to be associated with the entire class of SGLT-2 inhibitors, only with INVOKANA/INVOKAMET. Therefore, this safety communication and the black box warning was not for the entire class of SGLT-2 inhibitors, but was solely for INVOKANA, INVOKAMET, and INVOKAMET XR. On June 12, 2017, results from a large study sponsored by Defendants and examining safety outcomes with Canagliflozin (CANVAS) was published in the *New England Journal of Medicine* that showed an increased risk of amputations in users of INVOKANA/INVOKAMET.

5. After beginning treatment with INVOKANA/INVOKAMET, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed a diabetic foot infection (osteomyelitis) necessitating an amputation of Plaintiff's right first toe through the metatarsophalangeal joint. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA/INVOKAMET has caused and will continue to cause injury and damage to Plaintiff. Plaintiff contends that the Defendants knew of this risk with INVOKANA/INVOKAMET, but failed to inform him or his doctor regarding this risk, and therefore brings this Complaint against Defendants

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

PARTIES

7. Plaintiff Bonnie Hamm ingested and was physically harmed by the Defendants' product. "Plaintiff" when used in the singular, refers to plaintiff Bonnie Hamm, the plaintiff that ingested INVOKANA/INVOKAMET and was physically harmed.

8. At all relevant times since Bonnie Hamm's initial use of INVOKANA/INVOKAMET, Plaintiff was and is a resident and citizen of Gadsden, Tennessee, located in Crockett County.

9. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICIA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Janssen"), was at all relevant times, a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson and Johnson. At all times relevant and material hereto, Janssen was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including INVOKANA/INVOKAMET, in New Jersey and Tennessee and throughout the United States.

10. Janssen is registered to do business throughout the United States, including New Jersey and Tennessee, where Plaintiff resides and where Plaintiff was treated for her injuries.

11. Janssen, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of INVOKANA/INVOKAMET.

12. Janssen is the wholly owned subsidiary of Johnson & Johnson ("J&J"). J&J and Janssen worked together to achieve the common business purpose of selling and profiting from INVOKANA/INVOKAMET.

13. Janssen's President and Chief Executive Officer at all relevant times reports directly to a J&J Company Group Chairman, who in turn reports to J&J's Executive Committee and Board of Directors. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling INVOKANA/INVOKAMET.

14. J&J and Janssen executives were also members of a Pharmaceutical Global Operating Committee, through which J&J set overall corporate goals that guided Janssen's strategic and tactical plans for INVOKANA/INVOKAMET. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling INVOKANA/INVOKAMET.

15. J&J established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, J&J supervised and controlled corporate sales goals; drug research; development, and manufacturing; medical affairs; regulatory affairs and compliance; legal affairs; and public relations. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling INVOKANA/INVOKAMET.

16. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, is a limited liability company organized under the laws of New Jersey which has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ. Defendant Janssen Research & Development, LLC (formerly known as Johnson & Johnson Pharmaceutical Research and Development, LLC, and hereinafter referred to as "Janssen R&D"), is a New Jersey limited liability company. Janssen R&D is a wholly owned subsidiary of Centocor Research & Development, Inc., which is not a publically held corporation. Centocor Research & Development, Inc., a Pennsylvania corporation with its principal place of business in

Pennsylvania, Janssen R&D is registered to do business throughout the United States, including in New Jersey and Tennessee, where Plaintiff resides and where plaintiff Bonnie Hamm was treated for her injuries.

17. Janssen R&D is registered to do business throughout the United States, including in New Jersey where the case is filed and Tennessee where Plaintiff resides and where plaintiff Bonnie Hamm was treated for her injuries.

18. Janssen R&D, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of INVOKANA/INVOKAMET.

19. Defendant JOHNSON & JOHNSON (hereinafter "J&J"), is a fictitious name adopted by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling INVOKANA/INVOKAMET.

20. J&J, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of INVOKANA/INVOKAMET.

21. Defendant, JANSSEN ORTHO, LLC ("Ortho") is a Delaware limited liability company with a principal place of business at State road 933 Km 01, Street Statero, Gurabo, Puerto Rico 00778. Ortho is a wholly-owned subsidiary of Johnson & Johnson. At all times relevant hereto, Defendant Ortho manufactures, and continues to manufacture INVOKANA/INVOKAMET. At all times relevant hereto, Defendant Ortho derived, and

continues to derive, substantial revenue from goods and products developed, marketed, sold, distributed and disseminated and used in New Jersey, Tennessee and throughout the United States.

22. Ortho, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of INVOKANA/INVOKAMET.

23. At all times alleged herein, Defendants shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

24. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

25. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(b) because, at all times material hereto, a substantial part of the events or omissions giving rise to this claim occurred in this District, and 28 U.S.C. §1391(a) because at all times material hereto, Defendants JANSSEN and JOHNSON & JOHNSON had their principal place of business in this District, and all the defendants conducted substantial business in this District related to INVOKANA/INVOKAMET. Additionally, the Multi-District Litigation was created in and assigned to this District.

FACTUAL ALLEGATIONS

A. General Allegation

26. This action seeks, among other relief, general and special damages due to Plaintiff Bonnie Hamm suffering severe, life threatening and permanently debilitating side effect[s] of an amputation of the first toe of the right foot through the metatarsophalangeal joint caused by INVOKANA/INVOKAMET.

27. INVOKANA (also known as canagliflozin), and INVOKAMET (a combination of canagliflozin and metformin) are members of gliflozin class of pharmaceuticals also known as sodium glucose co-transporter 2 ("SGLT2") inhibitors.

28. SGLT2 inhibitors, including INVOKANA/INVOKAMET, inhibit renal glucose reabsorption through the SGL2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract instead of reabsorbed into the blood stream thereby putting additional strain on the kidneys.

29. SGLT2 inhibitors, including INVOKANA/INVOKAMET, are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose cotransporter receptors, including SGLT1.

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

31. The active ingredient in INVOKANA/INVOKAMET, canagliflozin is contained in both INVOKANA and INVOKAMET and has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States. This makes it unique among the class of SGLT2 inhibitors.

32. SGLT2 inhibitors, including INVOKANA/INVOKAMET, are currently approved only for improvement of glycemic control in adults with type 2 diabetes.

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

34. Defendant J&J, the parent company of Janssen, is involved in the marketing and branding of INVOKANA/INVOKAMET, and publishes marketing and warnings regarding the product.

35. Defendants published advertisements on their company websites and issued press releases announcing favorable information about Canagliflozin. For example, the FDA's approval of Canagliflozin (INVOKANA) on March 29, 2013 was announced on the J&J web site.

36. On April 1, 2013, Defendants announced the approval of Canagliflozin (INVOKANA) in the United States as a new treatment option for Type 2 diabetes. On March 14, 2016, J&J issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcement did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions. Neither announcement contained any warnings about the increased risk of amputations.

37. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities nationally including towards residents of Tennessee and New Jersey.

38. The INVOKANA/INVOKAMET-related pages on the Defendants' web sites are accessible from within Tennessee and New Jersey, and have been indexed by search engines so that they are located through searches that are conducted from within Tennessee and New Jersey.

39. Defendant J&J also published information touting the strong sales of INVOKANA/INVOKAMET in its corporate reports and in earnings calls.

40. Further, J&J employees had responsibility for overseeing promotion strategies for the drug INVOKANA/INVOKAMET.

41. Materials including advertisements, press releases, web site publications, and other communications regarding INVOKANA/INVOKAMET are part of the labeling of the drug, and could be altered without prior FDA approval.

42. Defendant J&J had the ability and the duty to improve the labeling of INVOKANA/INVOKAMET to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infections such as urosepsis as well as gangrene leading to amputations.

43. Defendant J&J so substantially dominates and controls the operations of Janssen and Janssen R&D that it could have required them to make changes to the safety label of the drug INVOKANA/INVOKAMET.

44. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of INVOKANA/INVOKAMET and direct these activities on behalf of J&J, Janssen, and Janssen R&D.

45. In fact, J&J so substantially dominates and controls the operations of Janssen and Janssen R&D, that the entities are indistinct for purposes of this litigation such that Janssen and Janssen R&D should be considered agents or departments of J&J, and J&J is their alter-ego.

46. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing right to INVOKANA/INVOKAMET in North America, and marketed, advertised, distributed, and sold INVOKANA/INVOKAMET in Tennessee and New Jersey and the remainder of the United States.

47. In February, 2014, Janssen R&D submitted an NDA to the FDA for approval to market INVOKANA in the United States.

48. In August 2014, the FDA approved INVOKANA as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

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

50. In an effort to increase sales and market share, Defendants have aggressively marketed and continue to aggressively market INVOKANA/INVOKAMET to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in type 1 diabetics.

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

52. Defendants' marketing campaign willfully and intentionally misrepresented the risks of INVOKANA/INVOKAMET and failed to warn about the risks of diabetic ketoacidosis, kidney failure, sepsis, amputation and other injuries.

53. INVOKANA/INVOKAMET is one of Defendants' top selling drugs, with annual sales exceeding $1 billion.

54. In September 2015, the FDA announced that SGLT2 inhibitors cause premature bone loss and fractures.

55. In December 2015, the FDA announced that SGLT2 inhibitors cause diabetic ketoacidosis, pyelonephritis (kidney infections), and urosepsis.

56. In May 2016, the FDA announced that SGLT2 inhibitors have been linked to an increased risk of amputations.

57. In June 2016, the FDA announced that SGLT2 inhibitors cause severe renal impairment, angioedema, and anaphylaxis.

58. In May of 2017 the FDA confirmed that INVOKANA and INVOKAMET increase the risk of leg and foot amputations and required a black box warning, as well as announcing further investigation into this safety issue.

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

60. Defendants, both individually and in concert with one another, misrepresented that INVOKANA/INVOKAMET is a safe and effective treatment for type 2 diabetes mellitus

when in fact the drug causes serious medical problems which require hospitalization and can lead to debilitating and/or life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, sepsis and kidney failure and its sequelae and amputations of the toes, feet and legs.

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

a. Canagliflozin selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given canagliflozin;

c. Studies of SGLT1 inhibitor phlorizin, and its propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, an indication of a propensity to develop ketoacidosis;

e. Clinical studies demonstrating increases in glucagon in people taking canagliflozin;

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

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

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

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

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

k. Clinical studies and adverse event reports demonstrating an increased rate of reports of patients developing gangrene, diabetic foot ulcers, lower limb ischemia and running the risk of and/or actually requiring an amputation.

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

63. Amputations lead to loss of mobility further exacerbating the risks of a sedentary lifestyle, including but not limited to weight gain, cardiovascular risks, pressure ulcers and resulting dangerous infections, as well as the physical and economic requirements of adapting to life in a wheelchair, such as ramps, bathroom and kitchen alterations, the inability to drive or costs needed for vehicle adaptations, cost for prosthetics and impaired earning potential.

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

65. Defendants were aware that the mechanism of action for INVOKANA/INVOKAMET places extraordinary strain on the kidneys and renal system. They were also aware that INVOKANA/INVOKAMET use causes volume depletion and that, as with thiazide diuretics, this could lead to increased risk of gangrene, diabetic foot ulcers, lower limb ischemia and eventually amputation of toes, feet and legs below the knee.

66. On June 12, 2017 the *New England Journal of Medicine* published results from the Canagliflozin Cardiovascular Assessment Study ("CANVAS") which integrated data from two trials involving a total of 10,142 patients. CANVAS reported that the risk of lower limb amputations was 5.9 amputations per 1.000 patients per year for canagliflozin compared to 2.8 amputations per 1,000 patients per year for placebo. Defendants, who sponsored and supported CANVAS, received and were aware of this data well before the publication date. Yet, despite this knowledge, they failed to make any changes to their label and failed to alert patients like Plaintiff and their physicians of this serious risk.

67. Despite their knowledge of data indicating that INVOKANA/INVOKAMET use is causally related to the development of diabetic ketoacidosis, kidney failure and amputations, Defendants promoted and marketed INVOKANA/INVOKAMET as safe and effective for persons such as Bonnie Hamm throughout the United States, including Tennessee and New Jersey.

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

69. Defendants failed to adequately warn consumers and physicians about the risks associated with INVOKANA/INVOKAMET and the monitoring required ensuring their patients' safety.

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

71. Consumers of INVOKANA/INVOKAMET and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, sepsis, amputations, and the life-threatening complications thereof.

72. Consumers, including Bonnie Hamm, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

B. Specific Allegations

73. Bonnie Hamm had several alternative and safer methods to treat Plaintiff's diabetes, including diet and exercise and other diabetes medications. Plaintiff was prescribed INVOKANA/INVOKAMET in or around May and June 2016 and used it as directed.

74. In May 2016, Bonnie Hamm was prescribed INVOKANA to be taken once daily to improve glycemic control as an adjunct to diet and exercise.

75. In June 2016, Bonnie Hamm was prescribed INVOKAMET to be taken twice daily to improve glycemic control as an adjunct to diet and exercise.

76. On or about approximately January 23, 2017, as a direct result of her treatment with INVOKANA/INVOKAMET, Bonnie Hamm was hospitalized for a diabetic foot ulcer and osteomyelitis of the first toe of the right foot.

77. On or about approximately January 25, 2017, as direct result of her use of INVOKANA/INVOKAMET, Bonnie Hamm underwent surgery for an amputation of the first toe of her right foot through the metatarsophalangeal joint.

78. Plaintiff was discharged from the hospital on or about approximately January 26, 2017.

79. Plaintiff endured pain and suffering, and will continue to endure pain and suffering as a result of her permanent disability, as well as emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

80. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused Bonnie Hamm's permanent injuries and damages.

81. Plaintiff's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life threatening and debilitating risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA/INVOKAMET. The conduct and the product defects were a substantial factor in bringing about Plaintiff's injuries.

82. Defendants had a duty to warn Plaintiffs's prescribing physicians about the risks of INVOKANA/INVOKAMET use, including the risk of diabetic ketoacidosis, renal failure, sepsis, resulting complications thereof as well as gangrene, diabetic foot ulcers, lower limb ischemia and amputations.

83. Had Plaintiff and Plaintiff's physicians known the risks associated with the use of SGLT2 inhibitors, including INVOKANA/INVOKAMET, Plaintiff would not have been

prescribed INVOKANA/INVOKAMET, would not have taken INVOKANA/INVOKAMET, and/or Plaintiff would have been adequately monitored for its side effects, and as a result, would not have suffered injuries and damages from using INVOKANA/INVOKAMET.

84. Plaintiff's prescribing and treating physicians relied on claims made by Defendants that INVOKANA/INVOKAMET has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through sales representatives detailing the product, print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through their comprehensive marketing campaigns.

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

86. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Plaintiff made an independent decision to use INVOKANA/INVOKAMET in reference to the overall benefits and risks communicated by Defendants.

87. Plaintiff's injuries were a reasonable foreseeable consequence of Defendants' conduct and INVOKANA/INVOKAMET's hazards, and were not reasonably foreseeable to Plaintiff or Plaintiff's physicians.

DELAYED DISCOVERY

88. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with INVOKANA/INVOKAMET.

89. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

90. The accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

91. Each Defendant is equitably stopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

CLAIMS FOR RELIEF

COUNT I
PRODUCT LIABILITY ACT – MANUFACTURING DEFECT
N.J.S.A. 2A:58C-1, *et seq.*)

92. Plaintiff restates the allegations set forth above as if fully rewritten herein.

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

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

95. At all times material to this action, INVOKANA/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:

a. When placed in the stream of commerce, INVOKANA/INVOKAMET contained manufacturing defects which rendered the subject 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

d. The subject product's manufacturing defects existed before it left the control of Defendants.

96. The subject product manufactured and/or supplied by Defendants was not reasonably fit, suitable or safe for its intended purpose because when it left Defendants' hands, it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae. In particular, the product is not safe, has numerous and serious side effects, and causes severe and permanent injuries including, but not limited to, having diabetic ketoacidosis, kidney failure, myocardial infarction, stroke, amputations, and other serious injuries and side effects.

97. As a result of INVOKANA/INVOKAMET's defective condition, Plaintiff suffered the injuries and damages alleged herein.

COUNT II
PRODUCT LIABILITY ACT – DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, *et seq.*)

98. Plaintiff restates the allegations set forth above as if fully rewritten herein.

99. INVOKANA/INVOKAMET is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

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

101. At all times material to this action, INVOKANA/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:

a. When placed in the stream of commerce, INVOKANA/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 subject product, including, but not limited to, permanent personal injuries including, but not limited to, diabetic ketoacidosis, kidney failure, myocardial infarction, stroke, amputations, and other serious injuries and side effects.;

b. When placed in the stream of commerce, INVOKANA/INVOKAMET was defective in design and formulation, making the use of INVOKANA/INVOKAMET more dangerous than an ordinary consumer

would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes;

c. The design defects of INVOKANA/INVOKAMET existed before it left the control of Defendants;

d. INVOKANA/INVOKAMET was insufficiently and inadequately tested;

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

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

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

103. As a result of INVOKANA/INVOKAMET's defective condition, Plaintiff suffered the injuries and damages alleged herein.

COUNT III
PRODUCT LIABILITY ACT – FAILURE TO WARN
(N.J.S.A. 2A:58C-1, *et seq.*)

104. Plaintiff restates the allegations set forth above as if fully rewritten herein.

105. INVOKANA/INVOKAMET was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings that were insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, having diabetic ketoacidosis and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for type 2 diabetes. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq*.

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

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

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

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

110. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

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

112. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, diabetic ketoacidosis, kidney failure, myocardial infarction, stroke, amputations, and other serious injuries and side effects.

113. Plaintiff, individually, and through Plaintiff's prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

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

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

COUNT IV
STRICT PRODUCTS LIABILITY - DESIGN DEFECT

116. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein

117. Defendants had a duty to properly design, manufacture, compound, test, inspect, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such steps as to assure that INVOKANA/INVOKAMET did not cause users to suffer from unreasonable and dangerous side effects.

118. The aforesaid product was defective and unsafe in design and manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Bonnie Hamm.

119. INVOKANA/INVOKAMET was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying INVOKANA/INVOKAMET failed to warn of the dangerous risks posed by INVOKANA/INVOKAMET, including the risk of developing diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

120. INVOKANA/INVOKAMET was defective and Defendants knew that INVOKANA/INVOKAMET was to be used by consumers without inspection for defects. Moreover, Plaintiff's prescribing physicians and other health care providers neither knew nor had reason to know at the time of Plaintiff's use of INVOKANA/INVOKAMET of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

121. INVOKANA/INVOKAMET was prescribed to and used by Plaintiff, Bonnie Hamm, as intended by Defendants and in a manner reasonably foreseeable to Defendants.

122. The design of INVOKANA/INVOKAMET was defective in that the risks associated with using INVOKANA/INVOKAMET outweighed any benefits of the design. Any benefits associated with the use of INVOKANA/INVOKAMET were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

123. The defect in design existed when the product left Defendants' possession.

124. At the time INVOKANA/INVOKAMET left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting INVOKANA/INVOKAMET.

125. As a result of INVOKANA/INVOKAMET's defective condition, Plaintiff suffered the permanent injuries and damages alleged herein.

COUNT V
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

126. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

127. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed INVOKANA/INVOKAMET in a defective and unreasonably dangerous condition, including the INVOKANA/INVOKAMET used by Plaintiff, Bonnie Hamm. The design defect made INVOKANA/INVOKAMET more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

128. INVOKANA/INVOKAMET's inadequate warnings rendered INVOKANA/INVOKAMET unreasonably dangerous and defective.

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

130. Plaintiff was prescribed and used INVOKANA/INVOKAMET for its intended purposes and for purposes that the defendants expected and could foresee.

131. Defendants expected and intended INVOKANA/INVOKAMET to reach, and did in fact reach, Bonnie Hamm without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

132. Plaintiff could not have discovered the unwarned risks of using INVOKANA/INVOKAMET through the exercise of reasonable care.

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

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

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

136. Defendants knew or should have known that the limited warnings disseminated with INVOKANA/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.

137. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug and failure to warn Plaintiff, Bonnie Hamm and Plaintiff's physicians about the significant risks inherent in INVOKANA/INVOKAMET therapy, Plaintiff sustained severe and permanent injuries.

COUNT VI
NEGLIGENCE

138. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

139. At all times relevant times, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of INVOKANA/INVOKAMET.

140. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of INVOKANA/INVOKAMET to cause or increase the harm of diabetic ketoacidosis, kidney failure, sepsis, and the life threatening complications of those conditions in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

141. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling INVOKANA/INVOKAMET.

142. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of INVOKANA/INVOKAMET to diabetic ketoacidosis, kidney failure, sepsis, and the life threatening complications of those conditions, in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

143. Defendants had a duty to accurately communicate the risks and benefits of INVOKANA/INVOKAMET to physicians, healthcare providers, and patients.

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

145. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including diabetic ketoacidosis, kidney failure and sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee; these injuries were foreseeable.

146. Plaintiff, Bonnie Hamm, did not know the nature and extent of the injuries that could result from INVOKANA/INVOKAMET and were misinformed about the benefits of INVOKANA/INVOKAMET and could not have discovered this information independently.

147. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling,

inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling INVOKANA/INVOKAMET, and failing to adequately test and warn of the risks and dangers of INVOKANA/INVOKAMET.

148. Despite the fact that Defendants knew or should have known that INVOKANA/INVOKAMET caused unreasonable, dangerous side effects, Defendants continued to market INVOKANA/INVOKAMET to consumers, including Plaintiff and Plaintiff's prescribing physicians, when there were safer alternative methods available.

149. Defendants' negligence was a foreseeable and proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, as described and prayed for herein.

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

151. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of the first toe of the right foot through the metatarsophalangeal joint and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services.

152. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also 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.

COUNT VII
BREACH OF IMPLIED WARRANTY

153. Plaintiff restates the allegations set forth above as if fully rewritten herein.

154. Defendants manufactured, distributed, advertised, promoted, and sold INVOKANA/INVOKAMET.

155. At all relevant times, Defendants knew of the use for which INVOKANA/INVOKAMET was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

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

157. INVOKANA/INVOKAMET was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA/INVOKAMET has dangerous propensities when used as intended and can cause serious injuries, including diabetic ketoacidosis, kidney failure, myocardial infarction, amputations, and stroke.

158. At all relevant times, Defendants intended that INVOKANA/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 INVOKANA/INVOKAMET was not adequately tested.

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

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

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

162. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell INVOKANA/INVOKAMET only if it was indeed of merchantable quality and safe and fit for its intended use.

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

164. Plaintiff and Plaintiff's physicians reasonably relied upon Defendants' implied warranty for INVOKANA/INVOKAMET when prescribing and ingesting INVOKANA/INVOKAMET.

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

166. INVOKANA/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.

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

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

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

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

171. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered amputation of the first toe of the right foot through the metatarsophalangeal joint and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services.

172. 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.

COUNT VIII
BREACH OF EXPRESS WARRANTY

173. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

174. Defendants expressly warranted to Plaintiff's physicians and Plaintiff by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians and the public that INVOKANA/INVOKAMET is safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

175. The "Warnings and Precautions" section of the INVOKANA/INVOKAMET prescribing information purports to expressly describe the relevant and material side-effects that Defendants knew or should have known about.

176. In particular the Consumer Medication Guide did not include any language that would suggest INVOKANA/INVOKAMET has been associated with diabetic ketoacidosis, kidney failure, blood infections, kidney infections, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

177. Plaintiff's physician prescribed INVOKANA/INVOKAMET and Plaintiff consumed INVOKANA/INVOKAMET reasonably relying on these warranties. Plaintiff and Plaintiff's physicians could not have learned independently that Defendants were false and misleading.

178. The product did not conform to representations made by the manufacturer.

179. Defendants knew or should have known that Plaintiff would rely on their warranties.

180. Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of the Defendants.

181. The warranties and representations are false because INVOKANA/INVOKAMET can cause diabetic ketoacidosis, kidney failure, blood infections, kidney infections, diabetic foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee.

182. INVOKANA/INVOKAMET does not conform to the Defendants' express representations; therefore, Defendants have breached the express warranties.

183. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Plaintiff's injuries and damages which are permanent.

COUNT IX
FRAUDULENT MISREPRESENTATION

184. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

185. Defendants intentionally and fraudulently misrepresented the safety and efficacy of INVOKANA in the product label. Specifically Defendants intentionally and fraudulently:

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

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

c. Upon information and belief, each and every advertisement and marketing channel fraudulently omits information about the risks of INVOKANA/INVOKAMET and overstates the benefits;

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

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

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

g. Failed to disclose that Defendants knew that INVOKANA/INVOKAMET was not adequately tested;

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

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

j. Affirmatively asserted that INVOKANA/INVOKAMET was safe and effective.

186. Defendants knew that their representations were false, yet they willfully, wantonly and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of INVOKANA/INVOKAMET to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

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

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

189. Defendants J&J, Janssen, and Janssen R&D, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug INVOKANA/INVOKAMET was generally well tolerated and safe for use, and was not likely to

cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, sepsis, or foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee. Plaintiff, Plaintiff's physicians, and others relied upon these representations.

190. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations Plaintiff suffered amputation of the first toe of the right foot through the metatarsophalangeal joint and other related health complications.

191. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also 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.

COUNT X
NEGLIGENT MISREPRESENTATION

192. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

193. Defendants made misrepresentations to Plaintiff's physicians, Plaintiff, and the general public from the time INVOKANA/INVOKAMET was first tested until now. The misrepresentation includes but is not limited to the misrepresentation that INVOKANA/INVOKAMET is safe, fit, and effective for human consumption.

194. Defendants owed a duty to Plaintiff to exercise reasonable care and ensure they did not misrepresent the safety or efficacy of INVOKANA/INVOKAMET.

195. Defendants failed to exercise that reasonable care and have therefore breached their duty to Plaintiff.

196. Defendants had a duty to correct these material misstatements because they knew or should have known the statements were false and others would reasonable rely on them and suffer injury.

197. These misrepresentations were made directly by the Defendants, by agents of the Defendants, and in written material directed to physicians, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of the subject product.

198. The representations by the Defendants were in fact false, in that INVOKANA/INVOKAMET is not safe, fit, and effective for human consumption, using INVOKANA/INVOKAMET is hazardous to health, and INVOKANA/INVOKAMET has a serious propensity to cause serious injuries to users, including but not limited to the injuries and damages suffered by Plaintiff as alleged herein.

COUNT XI
UNJUST ENRICHMENT

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

200. Plaintiff conferred a benefit on Defendants by purchasing INVOKANA/INVOKAMET.

201. Plaintiff, however, did not receive a safe and effective drug for which Plaintiff paid.

202. It would be inequitable for the Defendants to retain this money, because Plaintiff did not, in fact, receive a safe and efficacious drug.

203. By virtue of the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of the Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT XII
PUNITIVE DAMAGES ALLEGATIONS

204. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were wanton, willful, fraudulent, dishonest and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff, Bonnie Hamm, and other INVOKANA/INVOKAMET users and for the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA/INVOKAMET. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

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

206. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately

failed to remedy the known defects in INVOKANA/INVOKAMET and failed to warn the public, including Plaintiff, of the extreme risk of permanent injury occasioned by said defects inherent in INVOKANA/INVOKAMET. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of INVOKANA/INVOKAMET knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits. Said conduct was motivated by the reprehensible motive of increasing monetary profits for the sale of INVOKANA/INVOKAMET.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against each of the Defendants, and each of them individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Non-economic damages for an increased risk of future complications as a direct result of Plaintiff's injury;
5. Punitive damages;

6. Prejudgment interest at the highest lawful rate allowed by law;

7. Interest on the judgment at the highest legal rate from the date of judgment until collected;

8. Attorney's fees, expenses, and costs of this action; and

9. Such further relief as this Court deems necessary, just and proper.

DEMAND FOR A TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues and defenses.

DATED: December 26, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee
Dae Y. Lee
BERNSTEIN LIEBHARD LLP
10 E. 40th Street
New York, NY 10016
Tel: (212) 779-1414
Fax: (212) 779-3218
NJ Bar Identification No.: 033702012
dlee@bernlieb.com

Attorneys for Plaintiff

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

DATED: December 26, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee
Dae Y. Lee
BERNSTEIN LIEBHARD LLP
10 E. 40th Street
New York, NY 10016
Tel: (212) 779-1414
Fax: (212) 779-3218
NJ Bar Identification No.: 033702012
dlee@bernlieb.com