IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	MDL 2750 Master Docket No. 3:16-md-2750
KARYN NORRIS and PAUL NORRIS, Plaintiffs, JANSSEN PHARMACEUTICALS INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON CO., and 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. 3:17-cv-8075

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs file this Complaint pursuant to CMO No. 4, and are to be bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiffs, hereby designate the United States District Court for the District of Massachusetts as the place of remand as this case may have originally been filed there.

Plaintiffs, Karyn Norris and Paul Norris, bring this case against Defendants for injuries suffered as a direct result of Plaintiff Karen Norris' ingestion of the pharmaceutical product INVOKANA. Plaintiffs allege as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiffs 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 (at times referred to herein as "the subject product") for the treatment of diabetes.

2. Defendants Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Johnson & Johnson, and Janssen Ortho, LLC, concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

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

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inactions, Plaintiff Karyn Norris developed diabetic ketoacidosis. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiffs.

5. Plaintiffs bring this action for personal injuries suffered as a proximate result of Plaintiff Karyn Norris being prescribed and ingesting INVOKANA. Plaintiffs accordingly seek compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

6. Plaintiff Karyn Norris is a citizen and resident of Massachusetts.

7. Plaintiff Paul Norris is the spouse of Plaintiff Karyn Norris and a citizen and resident of Massachusetts.

8. Plaintiff Karyn Norris began taking INVOKANA on or about June 2014.

9. Defendant, 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 manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including INVOKANA, in Massachusetts and throughout the United States.

10. Janssen is registered to do business throughout the United States, including Massachusetts where Plaintiff resided and was treated.

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.

12. Janssen is a wholly owned subsidiary of Johnson and Johnson. Janssen and Johnson and Johnson worked together to achieve the common business purpose of selling INVOKANA.

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

14. Johnson and Johnson and Janssen executives were also members of a Pharmaceutical Global Operating Committee, through which Johnson and Johnson set overall corporate goals that guided Janssen's strategic and tactical plans for INVOKANA. At all relevant

times, Johnson & Johnson and Janssen worked together to achieve the common business purposes of selling INVOKANA.

15. Johnson and Johnson established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, Johnson and Johnson 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, Johnson and Johnson and Janssen worked together to achieve the common purposes of selling INVOKANA.

16. Defendant, Janssen Research & Development LLC ("Janssen R&D"). is a limited liability company organized under the laws of New Jersey which has its primal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ. Defendant 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 is registered to do business throughout the United States, including in Massachusetts, where Plaintiff resided and was treated.

17. 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.

18. Defendant Johnson and Johnson ("J&J") is a fictitious name adopted by Defendant Johnson and 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 J&J was engaged in the business of designing, developing,

manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling INVOKANA.

19. 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.

20. 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 whole owned subsidiary of J&J. At all times relevant hereto, Defendant Ortho manufactured, and continues to manufacture, INVOKANA. 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 Massachusetts and throughout the United States.

21. 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.

22. At all times alleged herein, Defendants shall include any and all named or unmapped parent companies, parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and any organization 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

23. 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.

24. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(a) because, at all times material hereto, Defendants had their principal place of business is in this district and Defendants conducted substantial business in this district. Additionally, the Multi-District Litigation was created in and assigned to this District.

FACTUAL ALLEGATIONS

A. General Allegations

25. This action is brought for damages on behalf of Plaintiffs Karyn Norris and Paul Norris. Plaintiff Karyn Norris was prescribed and supplied with, received and has taken the prescription drug INVOKANA. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff Karyn Norris suffering severe and life-threatening side effects of diabetic ketoacidosis caused by INVOKANA.

26. INVOKANA is a member of a gliflozin class of pharmaceutical also known as sodium glucose co-transporter 2 ("SGLT2") inhibitors.

27. SGLT2 inhibitors, including INVOKANA, 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.

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

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

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

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

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

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

34. Indeed, Defendants published advertisements on their company website and issued press releases announcing favorable information about INVOKANA. For example, the FDA's approval of INVOKANA on March 29, 2013 was announced on the J&J website. On March 14, 2016, J&J issued a press release announcing "First Real-Work Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Show Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcements did not

contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

35. Through these advertisements, press releases, publications and websites, J&J has purposefully directed activities nationally including towards residents of Massachusetts.

36. The INVOKANA-related pages on Defendants' websites are accessible from within Massachusetts and have been indexed by search engines so that they are located through searches that are conducted from within Massachusetts.

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

38. Further, J&J employees had responsibility for overseeing promotion strategies for the drug INVOKANA.

39. Materials, including advertisements, press releases, website publications, and other communications regarding INVOKANA are part of the labeling of the drug and could be altered without prior FDA approval.

40. Defendant J&J had the ability and the duty to improve the labeling of INVOKANA to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, etc.

41. 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.

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

43. 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.

44. Defendant Janssen, a whole owned subsidiary of J&J acquired the marketing right to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in Massachusetts and the remainder of the United States.

45. In May 2012, Janssen R&D submitted an NDA to the FDA for approval to market INVOKANA in the United States.

46. In March 2013, the FDA approved INVOKANA as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

47. As part of its marketing approval of INVOKANA, 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 safety and efficacy study.

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

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

50. Defendants' marketing campaign willfully and intentionally misrepresented the risks of INVOKANA and failed to warn about the risks of diabetic ketoacidosis, acute kidney injury, and other injuries.

51. INVOKANA is one of the Defendants 'top selling drugs, with annual sales exceeding $1 billion.

52. In September 2015, the FDA announced that INVOKANA causes premature bone loss and fractures.

53. In December 2015, the FDA announced that INVOKANA causes diabetic ketoacidosis, pyelonephritis (kidney infections), and urosepsis.

54. In March 2016, the FDA announced that INVOKANA causes severe renal impairment, angioedema, and anaphylaxis.

55. In May 2016, the FDA announced that INVOKANA has been linked to an increased risk of amputations.

56. At all times 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 injuries suffered by Plaintiff Karyn Norris herein.

57. Defendants, both individually and in concern with one another, misrepresented that INVOKANA is a safe and effective treatment for type 2 diabetes mellitus when, in fact, the

drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae and kidney failure and its sequelae.

58. 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. INVOKANA selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given INVOKANA;

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

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

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

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

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

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

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

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

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

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

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

62. Despite their knowledge of data indicating that INVOKANA use is casually related to the development of diabetic ketoacidosis and kidney failure, Defendants promoted and marketed INVOKANA as safe and effective for persons, such as Karyn Norris, throughout the United States, including Massachusetts.

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

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

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

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

67. Consumers, including Karyn Norris, have several alternative safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

B. Specific Allegations

68. Plaintiff Karyn Norris had several alternative and safer methods to treat diabetes, including diet and exercise and other diabetes medications. Plaintiff was prescribed INVOKANA in or around June 2014 by her doctor and used it as directed.

69. After approximately five (5) months of use and as a direct result of Plaintiff's treatment with INVOKANA, Plaintiff Karyn Norris was admitted to Malborough Hospital on or about October 26, 2014 with symptoms of shortness of breath and vomiting.

70. Plaintiff Karyn Norris was ultimately diagnosed with severe ketoacidosis.

71. Plaintiffs endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment. Plaintiffs seek actual, compensatory, and punitive damages from Defendants.

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

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

74. Defendants had a duty to warn Plaintiff Karyn Norris' prescribing physicians about the risks of INVOKANA use, including the risk of diabetic ketoacidosis and resulting complications.

75. Had Plaintiff and Plaintiff's physicians known the risks associated with the use of SGLT2 inhibitors, including INVOKANA, Plaintiff Karyn Norris would not have been prescribed INVOKANA and would not have taken INVOKANA, and/or Plaintiff Karyn Norris would have been adequately monitored for its side effects and as a result, would not have suffered injuries and damages from using INVOKANA.

76. Plaintiff Karyn Norris' prescribing and treating physicians relied on claims made by Defendants that INVOKANA has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through 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.

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

78. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Plaintiff Karyn Norris made an independent decision to use INVOKANA based on the overall benefits and risks communicated by Defendants.

79. Plaintiffs' injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's hazards, and were not reasonably foreseeable to Plaintiffs or Plaintiff Karyn Norris' physicians.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

80. Plaintiffs repeat, reiterate and reallege 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.

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

82. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of INVOKANA into interstate commerce in that Defendants

knew or should have known that using INVOKANA created a high risk of unreasonable, dangerous side effects, including stroke, heart attack, ketoacidosis, and severe kidney damage, 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.

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

a. Manufacturing, producing, promoting, formulating, creating, and/or designing INVOKANA without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing INVOKANA without adequately testing it;

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

d. Selling INVOKANA without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiffs, the public, the medical and healthcare profession, and the FDA of the dangers of INVOKANA;

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

g. Failing to test INVOKANA and/or failing to adequately, sufficiently and properly test INVOKANA.

h. Negligently advertising and recommending the use of INVOKANA without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that INVOKANA was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that INVOKANA had equivalent safety and efficacy as other forms of treatment for diabetes;

k. Negligently designing INVOKANA in a manner which was dangerous to its users;

l. Negligently manufacturing INVOKANA in a manner which was dangerous to its users;

m. Negligently producing INVOKANA in a manner which was dangerous to its users;

n. Negligently assembling INVOKANA in a manner which was dangerous to its users;

o. Concealing information from the Plaintiffs in knowing that INVOKANA was unsafe, dangerous, and/or non-conforming with FDA regulations;

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

84. Defendants underreported, underestimated and downplayed the serious dangers of INVOKANA.

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

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

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

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

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of INVOKANA;

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

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

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

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

h. Were otherwise careless and/or negligent.

87. Despite the fact that Defendants knew or should have known that INVOKANA caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell INVOKANA to consumers, including the Plaintiff Karyn Norris.

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

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

90. As a result of the foregoing acts and omissions, Plaintiffs, including Plaintiff Karyn Norris suffered serious and dangerous side effects including diabetic ketoacidosis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain

and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

92. Plaintiffs repeat, reiterate and reallege 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.

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

94. Defendants expressly represented to Plaintiff Karyn Norris, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that INVOKANA:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects, and

d. had been adequately tested and found to be safe and effective for the treatment of diabetes.

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

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

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

98. The representations about INVOKANA contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part

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

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

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

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

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

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

104. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Karyn Norris suffered severe ketoacidosis. In addition, Plaintiff Karyn Norris requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiffs, including Plaintiff Karyn Norris, also have 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.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

105. Plaintiffs repeat, reiterate and reallege 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.

106. Defendants have each willfully deceived Plaintiff Karyn Norris by concealing from her and her health care providers material facts concerning INVOKANA, which they had a duty to disclose.

107. Throughout the relevant time period, Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of INVOKANA.

108. Defendants fraudulently concealed information with respect to INVOKANA in the following particulars:

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

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

information which demonstrated that INVOKANA was not safer than alternatives available on the market.

c. Defendants were under a duty to Plaintiff, Karyn Norris, to disclose and warn of the defective and dangerous nature of INVOKANA because:

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

e. Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public; and

f. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of INVOKANA from Plaintiff Karyn Norris.

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

110. The facts concealed or not disclosed by Defendants to Plaintiff Karyn Norris were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use INVOKANA.

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

112. The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff Karyn

Norris, rely upon them so that Plaintiff Karyn Norris would request and purchase INVOKANA and Plaintiff's health care providers would prescribe and recommend INVOKANA.

113. Plaintiff Karyn Norris, her doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA.

114. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff Karyn Norris and her physicians would not have prescribed or ingested the drug.

115. Defendants, by concealment or other action, intentionally prevented Plaintiff Karyn Norris and her health care professionals from acquiring material information regarding the lack of safety of INVOKANA, thereby preventing Plaintiff Karyn Norris from discovering the truth. As such, Defendants are liable for fraudulent concealment.

116. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Karyn Norris suffered severe ketoacidosis. In addition, Plaintiff Karyn Norris requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiffs also have 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. Plaintiffs' 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.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(VIOLATION OF M.G.L. C.93A)

117. Plaintiffs repeat, reiterate and reallege 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.

118. M.G.L. c.93A, §2(a) prohibits unfair or deceptive acts or practices in the conduct of trade or commerce pursuant to state and federal law.

119. At all times relevant hereto, Defendants were engaged in trade or commerce throughout the United States, including the Commonwealth of Massachusetts, with respect to the design, manufacture, approval, marketing, promotion, distribution and sale of INVOKANA.

120. At all times material hereto, Defendants violated M.G.L. c. 93A, by, among other things, manufacturing, distributing and selling INVOKANA to consumers, including Plaintiff Karyn Norris, that was in a defective and unreasonably dangerous condition at the time the INVOKANA left Defendants' manufacturing plant, and by failing to disclose facts to Plaintiff Karyn Norris, and her physicians which might have influenced Plaintiff Karyn Norris not to use INVOKANA as a diabetes medication.

121. At the time these acts and omissions were made, Defendants knew or should have known that such conduct was in violation of M.G.L. c.93A, §2(a) and regulations promulgated thereunder.

122. As a result of Plaintiff Karyn Norris' reliance and as a direct and proximate cause of the Defendants' willful or knowing unfair or deceptive acts or practices, Plaintiff suffered serious injuries.

123. On October 4, 2017, Plaintiffs, through counsel, in compliance with M.G.L. c.93A, §9, sent a demand letter to Defendant.

124. As a result of violating M.G.L. c.93A, Defendants caused Plaintiff Karyn Norris to be prescribed and to use INVOKANA, causing Plaintiffs severe injuries and damages as previously described herein.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF WARRANTY – DEFECTIVE DESIGN)

125. Plaintiffs repeat, reiterate and reallege 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.

126. At all relevant times Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed INVOKANA, including the INVOKANA used by Plaintiff Karyn Norris, as described above.

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

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

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

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

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

c. INVOKANA was insufficiently tested;

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

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

f. Inadequate post-marketing surveillance; and/or

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

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

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

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

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

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

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

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

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

138. The harm caused by INVOKANA far outweighed its benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed INVOKANA to make it less dangerous. When Defendants designed INVOKANA, the state of the industry's scientific knowledge was such that a less risk design was attainable.

139. At the time INVOKANA left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff

Karyn Norris suffered without substantially impairing the reasonably anticipated or intended function of INVOKANA. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and considerably lower risk profile.

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

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

142. Due to the unreasonably dangerous condition of INVOKANA, Defendants are liable to Plaintiffs.

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

144. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Karyn Norris suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff Karyn Norris requires and will condition to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiffs have 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. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF WARRANTY – FAILURE TO WARN)

145. Plaintiffs repeat, reiterate and reallege 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.

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

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

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

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

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

151. This defect caused serious injury to Plaintiff Karyn Norris, who used INVOKANA for its intended purpose and in a reasonably anticipated manner.

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

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

154. Defendants had a continuing duty to warn Plaintiff Karyn Norris of the dangers associated with INVOKANA.

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

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

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

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

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

160. 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 was 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 risks of injuries with use of INVOKANA;

b. continued to aggressively promote INVOKANA even after Defendants knew or should have known of the unreasonable risks from use;

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with INVOKANA's capacity to cause its users to suffer diabetic ketoacidosis;

e. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of INVOKANA.

f. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and

g. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of INVOKANA.

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

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

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

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

165. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Karen Norris suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff Karyn Norris requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiffs have suffered and will continue to suffer diminished capacity for the enjoyment 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. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF WARRANTY – MANUFACTURING DEFECT)

166. Plaintiffs repeat, reiterate and reallege 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.

167. 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.

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

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

a. When placed in the stream of commerce, INVOKANA contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

c. The subject product was not made in accordance with Defendants' specifications or performance standards; and/or

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

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

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
LOSS OF CONSORTIUM

171. Plaintiffs repeat, reiterate and reallege 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.

172. At all relevant times Plaintiff Paul Norris was and is the spouse of Plaintiff Karyn Norris.

173. As a result of the injuries sustained by Plaintiff Karyn Norris, as set forth above, Plaintiff Paul Norris has suffered loss of consortium, including but not limited to, mental anguish and the loss of his wife's support, service, society, companionship, comfort, affection love and solace.

174. As a result of the injuries sustained by Plaintiff Karyn Norris, as set forth above, Plaintiffs sustained damage to their marital relationship.

PUNITIVE DAMAGES ALLEGATIONS

175. Plaintiffs repeat, reiterate and reallege 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.

176. Plaintiffs are 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 Plaintiff Karyn Norris, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with INVOKANA.

177. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks

associated with the use of INVOKANA, despite available information that INVOKANA was likely to cause serious side effects and/or complications.

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

179. 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.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above- referenced claims and Causes of Action and as follows:

1. Judgment for Plaintiffs and against Defendants;

2. Awarding compensatory damages to Plaintiffs for past and future damages,

including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

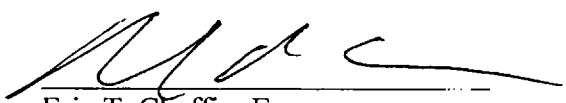
3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding Plaintiffs reasonable attorneys' fees;

5. Awarding Plaintiffs the costs of these proceedings; and

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

Respectfully Submitted,



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NJ Bar No. 019752001
Attorney for Plaintiffs

JS 44 (Rev. 12/12)

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

Karyn Norris and Paul Norris

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Roopal P. Luhana, Esq.
Chaffin Luhana LLP
600 Third Ave., 12th Fl., New York, NY 10016 (347) 269-4472

DEFENDANTS

JANSSEN PHARMACEUTICALS INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON CO., and JANSSEN ORTHO LLC.

County of Residence of First Listed Defendant Mercer County
(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)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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:
Plaintiff suffered personal injuries due to Defendants' defective product.

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Brian R. Martinotti DOCKET NUMBER MDL No. 2750

DATE
10/10/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/Roopal P. Luhana

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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 the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six 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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Karyn Norris and Paul Norris

Plaintiff(s)

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant(s)

Civil Action No. 3:17-cv-8075

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Rd.
Titusville, New Jersey 08560

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roopal P. Luhana, Esq.
Chaffin Luhana LLP
600 Third Ave, 12th Fl.
New York, NY 10016

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 3:17-cv-8075

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Karyn Norris and Paul Norris

Plaintiff(s)

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant(s)

Civil Action No. 3:17-cv-8075

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research & Development LLC
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roopal P. Luhana, Esq.
Chaffin Luhana LLP
600 Third Ave, 12th Fl.
New York, NY 10016

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 3:17-cv-8075

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Karyn Norris and Paul Norris

Plaintiff(s)

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant(s)

Civil Action No. 3:17-cv-8075

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson Co.
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roopal P. Luhana, Esq.
Chaffin Luhana LLP
600 Third Ave, 12th Fl.
New York, NY 10016

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 3:17-cv-8075

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

Karyn Norris and Paul Norris

Plaintiff(s)

v.

Janssen Pharmaceuticals, Inc., et al.

Defendant(s)

Civil Action No. 3:17-cv-8075

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Ortho LLC
933 Km 0 1
Street Statero
Gurabo, Puerto Rico 00778

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Roopal P. Luhana, Esq.
Chaffin Luhana LLP
600 Third Ave, 12th Fl.
New York, NY 10016

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 3:17-cv-8075

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: