**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF INDIANA**

PATRICIA MacMURRAY,

Plaintiff,

Civil Action No: 1:16-CV-2718

v.

JANSSEN PHARMACEUTICALS, INC., ELI LILLY AND COMPANY, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

COMPLAINT AND DEMAND FOR JURY TRIAL

Defendants

This action is brought by Plaintiff Patricia MacMurray who, by and through her undersigned counsel, brings this action seeking judgment against Janssen Pharmaceuticals, Inc., Eli Lilly and Company, and Boehringer Ingelheim Pharmaceuticals, Inc.[1] (collectively, Defendants) for injuries and damages caused by Plaintiff's ingestion of INVOKANA and JARDIANCE, which are type 2 diabetes drugs in the *gliflozin* class.

## INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold INVOKANA and JARDIANCE for the treatment of diabetes.

2. Defendants concealed, and continue to conceal, their knowledge of INVOKANA and JARDIANCE's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

[1] Eli Lilly and Company and Boehringer Ingelheim Pharmaceuticals, Inc. are the NDA holder, manufacturers, and distributors of Jardiance. Janssen Pharmaceuticals, Inc. is the NDA holder for Invokana.

3. As a result of the risky natures of both INVOKANA and JARDIANCE, persons who were prescribed and ingested INVOKANA and JARDIANCE, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including severe kidney damage and diabetic ketoacidosis, also known as DKA.

4. After beginning treatment with INVOKANA and JARDIANCE, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed DKA. Plaintiff's ingestion of the unreasonably dangerous drugs INVOKANA and JARDIANCE has caused and will continue to cause injury and damage to Plaintiff.

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

## PARTIES

6. At all times relevant hereto, Plaintiff Patricia MacMurray was a resident and citizen of the State of Utah, and was prescribed, purchased, ingested, and exposed to INVOKANA and JARDIANCE in the State of Utah. As a result of ingesting INVOKANA and JARDIANCE, Plaintiff suffered personal and economic injuries, which developed and occurred in the State of Utah, and Plaintiff sought and received treatment for the effects attendant thereto.

7. Defendant JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. JANSSEN PHARMACEUTICALS, INC. is the holder of the New Drug Application ("NDA") for INVOKANA.

8. Defendant ELI LILLY AND COMPANY is an Indiana corporation with its principal place of business at 893 S Delaware St, Indianapolis, IN 46225. Eli Lilly and Company is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug JARDIANCE.

9. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877. Boehringer Ingelheim Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug JARDIANCE.

10. Defendants are responsible for designing, developing, manufacturing, marketing, distributing, selling and otherwise introducing INVOKANA and JARDIANCE into the stream of commerce.

## JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 USC § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff is a resident and citizen.

12. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including INVOKANA and JARDIANCE, within the States of Utah and Indiana, with

a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

13. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and misleading information about INVOKANA and JARDIANCE to consumers, including Plaintiff, and to health care professionals in the States of Utah and Indiana, with a reasonable expectation that such information would be used and relied upon by consumers and health care professionals throughout the States of Utah and Indiana.

14. Defendants engaged in substantial business activities in the States of Utah and Indiana. At all relevant times, Defendants transacted, solicited, and conducted business in the States of Utah and Indiana through their employees, agents, and/or sales representatives and derived substantial revenue from such business in the States of Utah and Indiana.

15. Further, Eli Lilly is incorporated and has its principal place of business in the State of Indiana and has entered into contracts with Boehringer Ingelheim for the sale and distribution of Jardiance. As such, this Court has personal jurisdiction over all named defendants.

16. Venue of this case is proper in the Southern District of Indiana pursuant to 28 U.S.C. § 1391(b)(1) because Defendant Eli Lilly has its principal place of business in this District. Venue is further proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to Plaintiff's claims occurred in this District.

## FACTUAL BACKGROUND

17. On March 29, 2013, the FDA approved INVOKANA (canagliflozin) for use in treatment of type 2 diabetics. On August 1, 2014, the FDA approved JARDIANCE (dapagliflozin), also for use in treatment of type 2 diabetics. INVOKANA and JARDIANCE are

a part of the *gliflozin* drug class, and were among the first *gliflozins* approved for use in the United States. The *gliflozin* class is referred to generally as SGLT-2 (short for "Sodium Glucose Cotransporter 2") inhibitors.

18. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. SGLT-2 inhibitors reduce blood sugar levels by reducing glucose reabsorption through the user's kidneys and increasing glucose excretion through the user's urine.

19. SGLT-2 inhibitors, including INVOKANA and JARDIANCE, are indicated for only one use: lowering blood glucose in adults with type 2 diabetes.

20. SGLT-2 inhibitors, including INVOKANA and JARDIANCE, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

21. Though INVOKANA and JARDIANCE are indicated for only improved glycemic control in type 2 adult diabetics, in order to increase market share Defendants have marketed and continue to market INVOKANA and JARDIANCE to both healthcare professionals and direct to consumers for off label purposes, including but not limited to weight loss and reduced blood pressure.

22. Since INVOKANA and JARDIANCE's release, the FDA has received a significant number of reports of DKA among users of these drugs.

23. An analysis of the FDA adverse event database shows that patients taking one of the SGLT-2 inhibitors, including INVOKANA and JARDIANCE, are several times more likely to report ketoacidosis and/or severe kidney damage than those taking non-SGLT-2 diabetes drugs to treat diabetes.

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

25. Consumers, including Plaintiff, who have used INVOKANA and JARDIANCE for treatment of diabetes, have several alternative safer products available to treat the conditions.

26. Defendants knew of the significant risk of DKA and kidney damage caused by ingestion of INVOKANA and JARDIANCE. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity of such risks.

27. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote INVOKANA and JARDIANCE, and they willfully deceived Plaintiff, Plaintiff's health care professionals, the medical community, and the general public as to the health risks and consequences of the use of INVOKANA and JARDIANCE.

28. As a direct result of Defendants' above described conduct, Plaintiff was prescribed and began taking INVOKANA and JARDIANCE to treat type II diabetes.

29. Plaintiff ingested and used INVOKANA and JARDIANCE as prescribed and in a foreseeable manner.

30. The INVOKANA and JARDIANCE used by Plaintiff was provided in a condition substantially the same as the condition in which it was manufactured and sold.

31. Plaintiff agreed to initiate treatment with INVOKANA and JARDIANCE in an effort to reduce her blood sugar. In doing so, Plaintiff relied on claims made by Defendants that INVOKANA and JARDIANCE was safe and effective for the treatment of diabetes.

32. Instead, INVOKANA and JARDIANCE can cause severe injuries, including DKA.

33. Plaintiff began taking Invokana in early 2015, and began taking Jardiance on or about March 2015.

34. After beginning treatment with INVOKANA and JARDIANCE, and as a direct and proximate result thereof, Plaintiff suffered DKA on or about March 21, 2015 and was admitted to St. Marks Hospital. As a result of the injuries suffered, Plaintiff remained admitted to the hospital for seven days, including a stay in the Intensive Care Unit.

35. Defendants knew or should have known the risks associated with using INVOKANA and JARDIANCE, including the risk of developing DKA.

36. While Defendants did not warn about the risks of DKA, on May 15, 2015, the FDA issued a safety announcement covering the SGLT-2 inhibitor class, warning about the risk of DKA and advising that the FDA would continue to evaluate the safety issue.

37. As part of their continued evaluation, on December 4, 2015 the FDA issued a new safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT-2 inhibitors. The FDA noted adverse event reports "include only reports submitted to FDA, so there are likely additional cases about which we are unaware."

38. In light of the data disclosed in the December 4, 2015 safety communication, the FDA changed the label for INVOKANA, JARDIANCE, and the other SGLT-2 inhibitors to include a warning "about the risks of too much acid in the blood" and urged patients taking SGLT-2 inhibitors to stop taking the drug and seek immediate medical attention if they have any symptoms of ketoacidosis.

39. As part of their December 4, 2015 Safety Communication and label change, the FDA further required all manufacturers of SGLT-2 inhibitors, including Defendants, to conduct a postmarketing study wherein the manufacturers would analyze spontaneous postmarketing reports of ketoacidosis in patients treated with SGLT-2 inhibitors, including specialized follow-up to collect additional information, over a 5-year period.

40. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA and JARDIANCE. Defendants' conduct and the marketing and promotional defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's injuries.

41. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct.

42. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold INVOKANA and JARDIANCE both off-label and without adequate instructions or warning of serious side effects and unreasonably dangerous risks.

43. Plaintiff would not have used INVOKANA and JARDIANCE had Defendants properly disclosed the risks associated with its drug. Thus, had the defendants properly disclosed the risks associated with INVOKANA and JARDIANCE, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA and JARDIANCE.

44. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with taking INVOKANA and JARDIANCE.

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

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

## COUNT I
## PRODUCT LIABILITY – FAILURE TO WARN (STRICT LIABILITY)

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

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

49. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released INVOKANA and JARDIANCE into the stream of commerce. In the course of same, Defendants directly

advertised, marketed, and promoted INVOKANA and JARDIANCE to health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of INVOKANA and JARDIANCE.

50. Defendants expected INVOKANA and JARDIANCE to reach, and they did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the products from when they were initially distributed by the defendants.

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

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

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

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

55. Defendants negligently and recklessly marketed, labeled, distributed, and promoted INVOKANA and JARDIANCE.

56. Defendants had a continuing duty to warn Plaintiff of the dangers associated with INVOKANA and JARDIANCE.

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

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

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

60. INVOKANA and JARDIANCE, as supplied by Defendants, respectively, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

61. Each of the defendants knew or should have known that the limited warnings disseminated with INVOKANA and JARDIANCE were inadequate, but they failed to communicate adequate information on the dangers and safe use of their product, taking into

account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drugs. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render their products safe for ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the products for treatment of diabetes.

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

a. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of INVOKANA and JARDIANCE;

b. continued to aggressively promote INVOKANA and JARDIANCE 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 JARDIANCE 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 the severity of

INVOKANA and JARDIANCE's effect on renal function and propensity to cause 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;

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

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

64. Due to these deficiencies and inadequacies, INVOKANA and JARDIANCE was unreasonably dangerous and defective as advertised, sold, labeled, and marketed by Defendants, respectively.

65. Had Defendants properly disclosed and disseminated the risks associated with INVOKANA and JARDIANCE, Plaintiff would have avoided the risk of developing the injuries alleged herein.

66. Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of INVOKANA and JARDIANCE and the risks associated.

67. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered DKA and other related health complications.

68. In addition, as a result of the injuries caused by Defendants, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT II**
**NEGLIGENCE**

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

70. Defendants directly or indirectly caused INVOKANA and JARDIANCE to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

71. Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA and JARDIANCE, including the duty to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with INVOKANA and JARDIANCE.

72. 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 and JARDIANCE.

73. Defendants had a duty to disclose to health care professionals the causal relationship or association of INVOKANA and JARDIANCE to the development of Plaintiff's injuries.

74. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of INVOKANA and JARDIANCE, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of INVOKANA and JARDIANCE, including the injuries suffered by Plaintiff.

75. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold INVOKANA and JARDIANCE, they knew, or in the exercise of reasonable care should have known, that their products were defective, dangerous, and otherwise harmful to Plaintiff.

76. Defendants knew, or in the exercise of reasonable care should have known, that the use of INVOKANA and JARDIANCE could cause or be associated with Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

77. Defendants knew that many health care professionals were prescribing INVOKANA and JARDIANCE, and that many patients developed serious side effects including but not limited to DKA.

78. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion,

marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of INVOKANA and JARDIANCE in interstate commerce, in that the defendants knew and had reason to know that a consumer's use and ingestion of INVOKANA and JARDIANCE created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

79. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, and *dapagliflozin propanediol*, respectively, and they knew and were aware of the defects inherent in their product, failed to act in a reasonably prudent manner in designing, testing, and marketing their product, and failed to provide adequate warnings of their product's defects and risks.

80. Defendants failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test INVOKANA and JARDIANCE before releasing the drugs to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of INVOKANA and JARDIANCE;

c. failing to conduct sufficient post-market testing and surveillance of INVOKANA and JARDIANCE;

d. designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA and JARDIANCE to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the medication and without proper instructions to avoid foreseeable harm;

e. failing 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 JARDIANCE and the comparative severity of such adverse effects;

f. failing 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 the severity of INVOKANA and JARDIANCE's effect on acid balance and renal function;

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

h. failing to exercise due care when advertising and promoting INVOKANA and JARDIANCE; and

i. negligently continuing to manufacture, market, advertise, and distribute INVOKANA and JARDIANCE after they knew or should have known of their adverse effects.

81. Defendants had a duty to create products that were not unreasonably dangerous for their normal, common, and intended use.

82. Defendants negligently and carelessly breached this duty of care to Plaintiff because INVOKANA and JARDIANCE were and are unreasonably defective in design as follows:

a. INVOKANA and JARDIANCE unreasonably increase the risks of developing Plaintiff's injuries as complained of herein;

b. INVOKANA and JARDIANCE were not reasonably safe as intended to be used;

c. INVOKANA and JARDIANCE are more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. INVOKANA and JARDIANCE contained insufficient, incorrect, and defective warnings in that they failed to alert health care professionals and users, including Plaintiff, of the severity of the risks of adverse effects;

e. INVOKANA and JARDIANCE were not adequately tested; and/or

f. INVOKANA and JARDIANCE's risks exceeded any benefit of the drug.

83. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of the defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of INVOKANA and JARDIANCE.

84. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of INVOKANA and JARDIANCE.

85. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

86. Defendants' conduct, as described above, was reckless. The defendants' actions and inaction risked the lives of consumers and users of their product, including Plaintiff.

87. Defendants' INVOKANA and JARDIANCE were expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial

change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

88. At all times relevant hereto, INVOKANA and JARDIANCE were manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

89. Plaintiff used INVOKANA and JARDIANCE for its intended purposes and in a manner normally intended: to treat diabetes.

90. The harm caused by INVOKANA and JARDIANCE far outweighed the benefits, rendering both INVOKANA and JARDIANCE more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed INVOKANA and JARDIANCE to make them less dangerous. When the defendants manufactured INVOKANA and JARDIANCE, the state of the industry's scientific knowledge was such that a less risky design was attainable.

91. At the time INVOKANA and JARDIANCE left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of INVOKANA and JARDIANCE. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

92. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of INVOKANA and JARDIANCE and perceived the danger.

93. The defects in INVOKANA and JARDIANCE were substantial contributing factors in causing Plaintiff's injuries. But for the defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

94. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered DKA and other related health complications.

95. In addition, as a result of the injuries caused by Defendants, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

## COUNT III
## WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE

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

97. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that the defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability

and magnitude of the potential harm to others, the defendants' conduct involved an extreme degree of risk.

98. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and her healthcare providers.

99. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

100. Plaintiff therefore asserts claims for exemplary damages.

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

102. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and the defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of INVOKANA and JARDIANCE. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of INVOKANA and JARDIANCE, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting INVOKANA and JARDIANCE, despite their knowledge and awareness of these serious side effects and risks.

103. Defendants had knowledge of, and were in possession of evidence demonstrating that INVOKANA and JARDIANCE caused serious side effects. Notwithstanding their knowledge, Defendants continued to market INVOKANA and JARDIANCE by providing false and misleading information with regard to their products' safety to regulatory agencies, the medical community, and consumers of INVOKANA and JARDIANCE.

104. Although Defendants knew or recklessly disregarded the fact that INVOKANA and JARDIANCE cause debilitating and potentially lethal side effects, the defendants continued to market, promote, and distribute INVOKANA and JARDIANCE to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

105. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing INVOKANA and JARDIANCE and consumers from purchasing and ingesting INVOKANA and JARDIANCE, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming INVOKANA and JARDIANCE.

106. Defendants knew of INVOKANA and JARDIANCE's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drugs to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by INVOKANA and JARDIANCE.

107. Defendants' acts, conduct, and omissions were willful and malicious. The defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other users of INVOKANA and JARDIANCE and for

the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA and JARDIANCE. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all defendants in an amount appropriate to punish and make an example out of each.

108. Prior to the manufacture, sale, and distribution of INVOKANA and JARDIANCE, Defendants knew that INVOKANA and JARDIANCE were in a defective condition and knew that those who were prescribed the medications would experience and did experience severe physical, mental, and emotional injuries. Further, each defendant, through their officers, directors, managers, and agents, knew that INVOKANA and JARDIANCE presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of INVOKANA and JARDIANCE to risk of injury.

109. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing the defendants' profits, knowingly and deliberately failed to remedy the known defects in INVOKANA and JARDIANCE and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their respective agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of INVOKANA and JARDIANCE knowing these actions would expose persons to serious danger in order to advance the defendants' pecuniary interest and monetary profits.

110. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff prays for relief and judgment against 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. Attorneys' fees, expenses, and costs of this action; and

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

**JURY DEMAND**

Plaintiff demands trial by jury on all issues within this Petition.

Dated: October 10, 2016

Respectfully submitted,

HOVDE DASSOW & DEETS, LLC

/s/ Robert T. Dassow
Robert T. Dassow, #15145-64
10201 N. Illinois Street, Suite 500
Indianapolis, In 46290
Telephone: (317) 818-3100
Fax: (317) 818-3111
Email: rdassow@hovdeawl.com

Of Counsel:
JOHNSON BECKER, PLLC
Timothy J. Becker, Esquire
MN Bar No. 256663
Rolf T. Fiebiger, Esquire
MN Bar No. 391138
JOHNSON BECKER, PLLC
444 Cedar Street, Suite 1800
St. Paul, MN 55101
(612) 436-1800/ (612) 436-1801 (fax)
tbecker@johnsonbecker.com
rfiebiger@johnsonbecker.com
*Counsel for Plaintiff*

JS 44 (Rev 09/10)

# UNITED STATES DISTRICT COURT
# SOUTHERN DISTRICT OF INDIANA

CIVIL COVER SHEET Case No. 1:16-cv-2718

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law.

## Plaintiff(s):

First Listed Plaintiff:
Patricia MacMurray ;
2 Citizen of Another State; Utah
**County of Residence:** Outside This District

## Defendant(s):

First Listed Defendant:
Janssen Pharmaceuticals ;
5 Incorporated and Principal Place of Business in Another State; New Jersey
**County of Residence:** Outside This District

Additional Defendants(s):
Eli Lilly and Company ;
4 Incorporated or Principal Place of Business in This State;

Boehringer Ingelheim Pharmaceuticals, Inc. ;
5 Incorporated and Principal Place of Business in Another State; Connecticut

**County Where Claim For Relief Arose:** Marion County

## Plaintiff's Attorney(s):

Robert Dassow (Patricia MacMurray)
Hovde Dassow & Deets, LLC
201 W 103rd Street, Suite 500
Indianapolis, Indiana 46290
**Phone:** 3178183100
**Fax:** 3178183111
**Email:** rdassow@hovdelaw.com

## Defendant's Attorney(s):

Unknown ( Janssen Pharmaceuticals)

, Indiana
**Phone:**
**Fax:**
**Email:**

**Basis of Jurisdiction:** 4. Diversity of Citizenship

**Citizenship of Principal Parties** (Diversity Cases Only)

**Plaintiff:** 2 Citizen of Another State

**Defendant:** 5 Incorporated and Principal Place of Business in Another State

**Origin:** 1. Original Proceeding

**Nature of Suit:** 367 Health Care/Pharmaceutical Product Liability
**Cause of Action:** 28 USC 1332
**Requested in Complaint**

**Class Action:** Not filed as a Class Action

**Monetary Demand (in Thousands):** 75

**Jury Demand:** Yes

**Related Cases:** Is NOT a refiling of a previously dismissed action

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**Signature:** s/Robert Dassow

**Date:** 10/10/2016

If any of this information is incorrect, please close this window and go back to the Civil Cover Sheet Input form to make the correction and generate the updated JS44. Once corrected, print this form, sign and date it, and submit it with your new civil action.

# United States District Court

for the
Southern District of Indiana

| | | |
|---|---|---|
| PATRICIA MacMURRAY | ) | |
| | ) | |
| *Plaintiff,* | ) | |
| | ) | |
| vs. | ) | Cause No: 1:16-cv-2718 |
| | ) | |
| JANSSEN PHARMACEUTICALS, INC., | ) | |
| ELI LILLY AND COMPANY, and | ) | |
| BOEHRINGER INGELHEIM | ) | |
| PHARMACEUTICALS, INC., | ) | |

*Defendants.*

**SUMMONS IN A CIVIL ACTION**

TO: (*Defendants' names and addresses*)

ELI LILLY AND COMPANY
893 S Delaware St
Indianapolis, IN 46225

Boehringer Ingelheim
Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

JANSSEN
PHARMACEUTICALS, INC.
1125 Trenton-Harbourton Road
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:

Robert T. Dassow
HOVDE DASSOW & DEETS, LLC
10201 N Illinois Street, Suite 500
Indianapolis, IN 46290
Telephone: (317) 818-3100
Facsimile: (317) 818-3111
Email: rdassow@hovdelaw.com

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 Number: _____

**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 $_____.

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.