UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JOHN GROGAN AND VICTORIA GROGAN Plaintiffs, VS. BRISTOL-MYERS SQUIBB CO., ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA PLC, AND ASTRAZENECA AB, Defendants.	)	CASE NO.: 1:18-cv-00224

COMPLAINT AND DEMAND FOR JURY TRIAL

NATURE OF ACTION

COME NOW, the Plaintiffs, John Grogan and Victoria Grogan, individually, complaining against Defendants Bristol-Myers Squibb Co., Astrazenecal LP, Astrazeneca Pharmaceuticals LP, Astrazeneca PLC, and Astrazeneca AB (collectively "Defendants", and in support thereof states as follows:

1. Farxiga (dapagliflozin) and Xigduo (dapagliflozin and metformin extended-release) are sodium-glucose contransporter-2 (SGLT2) inhibitors approved for use, with diet and exercise, to lower blood sugar in adults with type 2 diabetes. Defendants have known for several years that these drugs cause diabetic ketoacidosis ("DKA") and severe kidney injury, as are now well documented in scientific journals, articles, and presentations and as explained by the mechanism of action of the medications. Despite this knowledge, the Defendants failed to warn patients and healthcare providers of the risk of developing DKA or serious kidney injury and upon information and belief, failed to accurately and timely report these risks to the Food and Drug Administration ("FDA").

2. Plaintiffs are consumers who were diagnosed with diabetes, used Farxiga and/or Xigduo XR for the treatment of their diabetes, and suffered from DKA or severe kidney injury, side effects for which they were not warned and were wholly unprepared. Had Plaintiffs and Plaintiffs' healthcare providers been provided an adequate warning that DKA and/or severe kidney injury could result, they would have selected a different treatment option from the numerous, safer, and effective alternatives to these drugs, or they would have implemented different monitoring and treatment protocols to enable early diagnosis of impending DKA or Acute Kidney Injury and would have warned their patients of the risks and obtained informed consent to proceed with the prescription of said medications if appropriate

3. As a result of these undisclosed side effects, Plaintiffs have been severely injured.

4. Defendants failed to warn that DKA and severe kidney injury were adverse reactions of Fargixa and/or Xigduo XR and Plaintiffs were unable to weigh these life-threatening possibilities when deciding among treatment options. As such, Plaintiffs seek recovery for the physical and mental suffering and economic damages caused by these drugs.

5. Furthermore, Defendants' *dapagliflozin* products, Farxiga and Xigduo XR, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants were defective in design and formulation when they were placed in the stream of commerce.

THE PARTIES - PLAINTIFFS

6. Plaintiff John R. Grogan is and was at all times relevant hereto a resident and citizen of Plainfield, Indiana.

7. At all relevant times hereto, Plaintiff Victoria Grogan was the wife of Plaintiff John Grogan.

8. Plaintiffs have suffered personal injuries as a direct and proximate result of

Defendants' conduct and misconduct as described herein and in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Farxiga and/or Xigduo XR.

9. Plaintiffs file these lawsuits within the applicable statute of limitations period of having a reasonable basis to suspect that these medications caused the harm they sustained. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of their injuries as the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did they have reason to suspect that they had been injured, the cause of their injuries, or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

10. Additionally, Plaintiffs were prevented from discovering this information at an earlier date because Defendants failed to disclose to the public, the FDA, and the medical profession their knowledge of the risk of DKA and severe kidney injury associated with the use of Farxiga and/or Xigduo.

PARTIES - DEFENDANTS

11. Defendant Bristol-Myers Squibb Co., (BMS) is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York. BMS 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 drugs FARXIGA and XIGDUO.

12. Defendant AstraZeneca LP is a Delaware limited partnership with its principal place of business at1800 Concord Pike, Wilmington, Delaware 19803. The general and limited partners of AstraZeneca LP are (i) AstraZeneca Pharmaceuticals LP (described below); and (ii)

KBI Sub, Inc. KBI Sub, Inc. is a Delaware company with its principal place of business in New Jersey. Accordingly, for purposes of diversity jurisdiction, AstraZeneca LP is a citizen of Delaware and New Jersey. AstraZeneca LP 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 drugs FARXIGA and XIGDUO.

13. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership with its principal place of business at1800 Concord Pike, Wilmington, Delaware 19803. The general and limited partners of AstraZeneca Pharmaceuticals LP arei) AstraZeneca AB (described below), Zeneca Inc., Astra USA Inc., and Astra U.S. Holdings Corporation. Astra USA Inc., Zeneca Inc., and Astra U.S. Holdings Corporation are Delaware corporations with their principal places of business in Delaware. Accordingly, for purposes of diversity jurisdiction, AstraZeneca Pharmaceuticals LP is a citizen of Delaware. AstraZeneca Pharmaceuticals LP 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 drugs FARXIGA and XIGDUO.

14. AstraZeneca PLC is a United Kingdom corporation with its principal place of business in Cambridge, England. AstraZeneca PLC 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 drugs FARXIGA and XIGDUO.

15. AstraZeneca AB is a Swedish Corporation with its principal place of business in Sodertalje, Sweden. AstraZeneca AB 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 drugs FARXIGA and XIGDUO

16. Defendants are responsible for designing, developing, manufacturing, marketing, distributing, selling and otherwise introducing Farxiga and Xigduo XR into the stream of commerce.

JURISDICTION AND VENUE

17. Federal subject-matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a). Plaintiffs allege the existence of subject-matter jurisdiction, and absent objection, there is complete diversity among Plaintiffs and Defendants because Defendants are incorporated and have their principal places of business in states other than the states in which Plaintiffs are residents and citizens of Plainfield, Hendricks County, Indiana. In addition, the amount in controversy exceeds $75,000.

18. Defendants conducted meetings, telephone calls, conference calls, webinars, and email communications between the respective companies and also their consultants and agents involving the design, development regulatory actions, marketing and distribution of the drugs Farxiga and Xigduo XR, in the State of New York. Thirty clinical trials relating to dapagliflozin have been or currently are being conducted in the State of New York. As such, this Court has personal jurisdiction over all named defendants.

19. Thus, venue of this case is proper in the Southern District of Indiana pursuant to 28 U.S.C. § 1391(b)(2) because BMS is a resident of this District and a substantial part of the events giving rise to Plaintiffs' claims occurred in this district.

FACTUAL BACKGROUND

Development, Approval, and Labeling Changes to Farxiga and Xigduo XR

18. Farxiga and Xigduo XR are a part of the class of drugs known as SGLT2 inhibitors.

19. SGLT2 inhibitors, such as Farxiga and Xigduo XR, are approved for use in the treatment of type 2 diabetes to reduce blood sugar levels by causing the kidneys to remove sugar from the body through the urine.

20. The first SGLT2 inhibitor drug, to come to market in the United States, was Invokana in March of 2013.

21. Although SGLT2 inhibitor drugs represent a relatively new class of drugs, their history dates back nearly 180 years.

22. The very first SGLT2 inhibitor, phlorizin, was discovered by French chemist in approximately 1835. This naturally occurring SGLT2 inhibitor was originally derived from the bark of an apple tree.

23. A short time later, in approximately 1886, diabetes pioneer, Dr. Joseph von Mering, discovered that ingestion of phlorizin in dogs mimicked diabetes and resulted in glycosuria (excretion of glucose in the urine), polyuria (increase urine output) and weight loss.

24. Although phlorizin showed promise in regulating glycemic index it carried with it significant gastrointestinal problems. In addition, it was found to have poor bioavailability, meaning it was poorly absorbed by the body when ingested orally. As a result, the potential of phlorizin remained untapped for well over one hundred and fifty (150) years.

25. During the passage of 150 years, phlorizin was used in various research formats to understand more about the underlying interaction of phlorizin and glucose.

26. In 1997, Japanese researcher ascertained a way to utilize SGLT2 receptors in the body and their interaction with glucose.

27. From that time forward, pharmaceutical companies began work to produce SGLT2 inhibitor medications for the treatment of type 2 diabetes.

28. On May 25, 2007, Janssen Pharmaceuticals, Inc. opened an Investigational New

Drug Application for Invokana (canagliflozin). On May 31, 2012, Janssen submitted a NDA for Invokana which was subsequently approved by the FDA, on or about March 29, 2013.

29. On or about December 28, 2010, Bristol-Myers Squibb (BMS) submitted a New Drug Application (NDA) for Farxiga (dapagliflozin).

30. However, upon reviewing the data contained in BMS's initial submission, the FDA found that the data did not support the conclusion that the benefits of Farxiga outweighed its risks. As a result, the FDA issued a Complete Response Letter on January 17, 2012, regarding its concerns, namely Farxiga induced liver injury, lack of efficacy in patients with moderate to severe renal impairment, cancer risks, and cardiovascular risk. Although, BMS filed a Formal Dispute Resolution Request in July of 2012, the appeal was denied by the FDA in September of 2012.

31. On or about July 11, 2013, BMS re-submitted a new 505(b)(1) drug application (otherwise known as an NDA) for Farxiga (dapagliflozin) seeking an indication for the use of Farxiga, along with diet and exercise, to improve glycemic control in adult patients with type 2 diabetes

32. On October 29, 2013, AstraZeneca AB submitted an NDA for Xigduo XR, which is dapagliflozin combined with metformin HCI extended-release, seeking an indication for use of Xigduo XR, along with diet and exercise, to improve glycemic control in adult patients with type 2 diabetes.

33. Finally, on January 8, 2014, the FDA approved FARXIGA (dapagliflozin) for use in treatment of type 2 diabetics. FARXIGA is a part of the *gliflozin* drug class, and was one of the first *gliflozins* approved for use in the United States. The *gliflozin* class is referred to generally as SGLT2 (short for "Sodium Glucose Cotransporter 2") inhibitors.

34. FARXIGA AND XIGDUO XR'S common active ingredient is *dapagliflozin propanediol.*

35. At the time of its approval, the label for Farxiga contained no warnings, precautions, post-marketing events, or adverse event reports related to DKA or severe acute kidney injury. Rather, the only mention of DKA contained in Farxiga's original label was that Farxiga should not be used to treat persons suffering from DKA. The original 2014 label was completely silent as to DKA being a possible adverse event or side effect associated with Farxiga. In addition, "kidney problems" was listed as a serious side effect, but the label contained no warnings specifying what type of kidney injuries and that the medication could cause the specific medical event known as "acute kidney injury".

36. Some of the common symptoms of DKA include excessive thirst, frequent urination, nausea and vomiting, abdominal pain, weakness or fatigue, shortness of breath, fruit-scented breath, dehydration, elevated blood sugar levels, and high ketones in the urine. The January 2014 labeling for Farxiga included data from clinical trials and adverse event reporting demonstrating increased urination, dehydration, and nausea as common side effects yet the labeling contained no mention of DKA as a potential risk.

37. Upon information and belief, Defendants would obscure the reporting of the adverse event of diabetic ketoacidosis by reporting it only as dehydration, nausea, vomiting, light headedness, volume depletion, or other such descriptions, but failed to categorize them as ketoacidosis even if such diagnosis was appropriate, thereby neglecting to adequately track adverse events associated with its products.

38. The same day Farxiga was approved by the FDA, on January 8, 2014, Defendants AstraZeneca and Bristol-Myers Squibb issued a press release noting prominently their New York stock exchange ticker, describing they have formed an "alliance" and have been working in collaboration to develop and commercialize a portfolio of medications for diabetes and related metabolic disorders that aim to provide treatment effects beyond glucose control. In

the same press release they announced an agreement under which AstraZeneca was to acquire Bristol-Myers Squibb's interests in the companies' diabetes alliance.

39. Five days later, on January 13, 2014 in another joint press release issued with both companies, AstraZeneca and BMS, prominently noting their New York stock exchange tickers, Brian Daniels, senior vice president, global development and medical affairs of Bristol- Myers Squibb touted "With the diabetes epidemic escalating and many people with type 2 diabetes struggling to reach their blood sugar goals, *Farxiga* offers an important new option for healthcare professionals and adult patients." "In clinical trials, *Farxiga* helped improve glycemic control, and offered additional benefits of weight and blood pressure reductions."

40. On Feb. 3, 2014, AstraZeneca announced that it completed the acquisition of Bristol-Myers Squibb's interests in the companies' "diabetes alliance." The acquisition gave AstraZeneca ownership of the intellectual property and global rights for development, manufacture, and commercialization of the diabetes business, which included Farxiga and Xigduo XR. On completion of the acquisition, AstraZeneca paid Bristol-Myers Squibb $2.7 billion of initial consideration. AstraZeneca has also agreed to pay up to $1.4 billion in regulatory, launch and sales payments, and various sales-related royalty payments up until 2025, $600 million of which relates to the approval of Farxiga in the US.

41. On October 29, 2014, FDA approved Xigduo, a combination drug therapy comprised of Farxiga (*dapagliflozin propanediol)*, a SGLT2 inhibitor, combined with *metformin hydrochloride*, for the treatment and regulation of glycemic index in type 2 diabetics.

42. At the time of its approval, the labeling for Xigduo XR indicated that it was contraindicated for use in patients suffering from DKA. However, the labeling contained no warnings, adverse event reports, precautions, or side effects related to DKA or severe acute

kidney injury associated with the use of Xigduo XR. Rather the label suggested that patients with type 2 diabetes, previously well controlled on Xigduo XR, who developed laboratory abnormalities or clinical illness should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. However, the labeling provided no warnings or precautions that Xigduo XR was associated with development of DKA or acute kidney injury.

43. While the Xigduo XR label described above was wholly inadequate to adequately warn a physician of the risk of DKA, it nevertheless reflects that Defendants were cognizant of some DKA issue yet they failed to update the Farxiga label to include comparable treatment instructions.

44. There are numerous other classes of diabetic medications that are safe and efficacious that have been widely used and are still very much in use. Indeed, the first line of treatment is exercise and diet and if that is not successful, the next line of treatment is the gold standard medication Metformin which has been safely used for many years. Beyond that there are other classes of diabetes medications that are utilized in the armament of endocrinologists and internists. However, upon the approval of the indication of Farxiga, Defendants sales representative were promoting the drug to doctors as a first line of treatment, in contrast to the standard of care.

45. As a result, SGLT2 inhibitors are widely prescribed. During the 12-month period from October 2014, when Xigduo XR was approved, to September 2015, approximately 1.7 million patients received a prescription for an SGLT2 inhibitor.

46. However, since the release of the first SGLT2 drug into the market, the FDA has received a significant number of post-marketing reports of diabetic ketoacidosis and acute kidney injuries among users of these class of drugs, including Farxiga and Xigduo XR.

47. An analysis of FDA adverse event database shows that patients taking one of the SGLT2 inhibitors, including Farxiga and/or Xigduo XR, are several times more likely to report ketoacidosis and/or severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

48. Although the Defendants failed to warn consumers of these risks, on May 15, 2015, FDA issued a safety announcement covering the SGLT2 inhibitor class, warning about the risk of diabetic ketoacidosis and advising that FDA would continue to evaluate the safety issue.

49. The data used in FDA's May 15, 2015 safety alert was collected from March 2013 to June 6, 2014. Upon information and belief, the Defendants knew or should have known of the data underlying the FDA's safety alert, and knew or should have known of the potential association between Farxiga and/or Xigduo XR and DKA and/or severe kidney injury prior to the FDA's safety announcement.

50. The data FDA used to issue its May 15, 2015 safety alert came from FDA Adverse Event Reporting System ("FAERS"), a publicly available database which Defendants, as manufacturers of a pharmaceutical drug submitted for approval and approved by FDA, is obligated to monitor for signals that the drug might be unsafe. The same kinds of signals that led FDA to issue its alert were ignored by Defendants.

51. As part of its 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 SGLT2 inhibitors. The FDA noted adverse event reports "include only reports submitted to FDA, so there are likely additional cases about which we are unaware."

52. It is well recognized in the pharmaceutical industry that reported adverse events are a very small percentage of the actual events that occur but do not get reported.

53. In light of the data disclosed in the December 4, 2015 Safety Communication, the FDA changed the label for FARXIGA, XIGDUO XR, and the other SGLT2 inhibitors to include a warning "about the risks of too much acid in the blood" and urged patients taking SGLT2 inhibitors to stop taking the drug and seek immediate medical attention if they have any symptoms of ketoacidosis.

54. As part of their December 4, 2015 Safety Communication and label change, FDA further required all manufacturers of SGLT2 inhibitors, including Defendants, to conduct a post-marketing study wherein the manufacturers must analyze spontaneous post-marketing reports of ketoacidosis in patients treated with SGLT2 inhibitors, including specialized follow-up to collect additional information, over a 5-year period.

55. Until the FDA required Defendants to change the Farxiga and Xigduo XR labels in December 2015, Defendants did not warn about Farxiga and Xigduo XR causing DKA and acute kidney injury.

56. On or about December 4, 2015, the Warnings and Precautions sections of the Farxiga and Xigduo XR labels were updated to include ketoacidosis. Specifically the warning states: "Ketoacidosis: Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected discontinue Farxiga [and/or Xigduo XR] evaluate and treat promptly. Before initiating Farxiga [and/or Xigduo XR], consider risk factors for ketoacidosis. Patients on Farxiga [and/or Xigduo XR] may require monitoring and temporary discontinuation for therapy in clinical situations known to predispose to ketoacidosis."

57. On June 14, 2016, the FDA issued a second Drug Safety Communication regarding Invokana, Invokamet, Farxiga, and Xigduo XR warning about the associated risk of developing acute kidney injury as a result of ingesting these SGLT2 inhibitors.

58. It was not until June 14, 2016 that labels for both Farxiga and Xigduo XR were updated to include warnings and precautions related to acute kidney injury and impairment of renal function stating that, dapagliflozin can cause renal impairment and confirming the post- marketing reports of acute kidney injury. Although prior labeling cautioned that patients with impaired renal functioning should be closely monitored, it did not warn that Farxiga and/or Xigduo XR were associated with the development of acute kidney injury.

59. Upon information and belief, Defendants would report adverse events of acute kidney injury and renal impairment as increased serum creatinine levels, decreased eGFR, intravascular volume contractions, and renal insufficiency, while avoiding describing the adverse event as the recognized clinical diagnosis of "acute kidney injury".

60. On August 17, 2016, the Warnings and Precautions sections of the Farxiga and Xigduo XR labels were again updated, this time to warn of the risk of fatal ketoacidosis. Specifically, the following language was added to the Warning: "Fatal cases of ketoacidosis have been reported in patients taking [FARXIGA/XIGDUO XR]."

61. Based upon information and belief, Defendants were aware of the increased risk for the development of diabetic ketoacidosis and/or severe kidney problems associated with SGLT2 inhibitors, including Farxiga and Xigduo XR, well before Plaintiffs in this litigation ingested Farxiga and/or Xigduo XR and suffered DKA and/or acute kidney injuries.

Farxiga and Xigduo XR are Defective by Design

62. Insulin production is triggered by glucose levels. Farxiga and Xigduo XR are defective as designed in that they decrease blood glucose levels in such an extreme manner that they prevent proper insulin production. Although Farxiga and/or Xigduo XR rid the body of glucose, they do not address the insulin supply/resistance problem faced by type 2 diabetics. Thus, when the body is depleted of glucose and insulin production is not triggered, the body begins to metabolize fat (lipolysis), which leads to the release of ketones and ketoacidosis.

63. Ingestion of Farxiga and/or Xigduo XR leads to an increase in the body's level of glucagon, which stimulates lipolysis, resulting in the release of ketones.

64. By design, Farxiga and/or Xigduo prevent the absorption of glucose in the proximal renal tubule causing glucose to be flushed out in the urine. This flushing of glucose through frequent urination leads to dehydration and salt depletion, which ultimately causes a reduction in blood pressure.

65. In order to maintain blood pressure, the body reacts by producing increased hormones designed to stimulate and increase blood pressure such as cortisol, epinephrine, and glucagon. The presence of these hormones induces lipolysis (the burning of fat), which can cause ketoacidosis.

66. Normally, ketones would be processed by the kidneys and excreted in urine, making identification of ketoacidosis relatively easy to ascertain. However, Farxiga and Xigduo XR can prevent the kidneys from excreting ketones in the urine. This can cause an increased buildup of ketones in the body and makes identification of ketoacidosis through urine sampling difficult.

67. The development of ketoacidosis is a life-threating injury, which left untreated, will result in death.

68. Along with the above described ketone related injuries, SGLT-2 inhibitors, and Farxiga and Xigduo XR in particular, also dramatically increase the likelihood of a patient developing kidney failure.

69. Farxiga and Xigduo XR by their very mechanism of action of increased frequent urination cause dehydration and osmotic diuresis. Osmotic diuresis is the increase of urination rate caused by the presence of certain substances in the small tubes of the kidneys. The excretion occurs when substances such as glucose enter the kidney tubules and cannot be reabsorbed.

70. Because Farxiga and Xigduo XR block sugar from being reabsorbed by the kidneys, the kidneys expel the sugar in the patient's urine. A buildup of sugar in the tubes leading from the kidneys leads to acute kidney (or "renal") failure.

71. Osmotic diuresis leads to volume depletion, which is water loss and salt loss. Volume depletion is distinct from dehydration, which relates only to water loss.

72. Volume depletion leads to decreased renal perfusion, meaning the kidneys do not push the fluid through its vessels as well as they should. Unimpeded, decreased renal perfusion leads to acute renal injury, including kidney failure which necessitates dialysis and, unencumbered, may require kidney transplants.

73. Farxiga and Xigduo XR causes osmotic diuresis due to their very mechanism of action, by forcing the kidneys to work harder and push more glucose through their tubules than the kidneys are intended to do. This continued heightened state the kidneys are put in when a patient is on Farxiga or Xigduo XR makes kidney injury a higher likelihood, even for those with normal kidney function at the beginning of Farxiga or Xigduo XR therapy.

74. Consumers, including Plaintiffs, who have used Farxiga and/or Xigduo XR for the treatment of diabetes, have several alternative and safer products available to treat their condition.

75. In particular, other diabetes drugs such as sulfonylureas and DPP-4s are drugs, effective in treating type 2 diabetes, which do not carry an increased risk for developing DKA.

76. Furthermore, within the SGLT2 inhibitor class, Jardiance is an alternative safer product available to treat type 2 diabetes, in that studies have shown it is more effective in lowering A1C than Farxiga, show to result in a larger weight loss than Farxiga, and it has an FDA approved indication for the reduction of cardiovascular deaths. Further, the FDA did not require the makers of Jardiance to change its label to warn of acute kidney injury, like it did Farxiga and Xigduo XR.

Defendants Have and Continue to Engage in Off-Label Promotion

77. SGLT2 inhibitors are a class of type 2 diabetes drugs more specifically referred to as sodium-glucose contrasporter-2 inhibitors. The SGLT2 class of drugs includes not only *dapagliflozin* drugs Farxiga and Xigduo XR, but also Invokana (*canagliflozin*), Invokamet (*canagliflozin* and *metformin*), Jardiance (*empagliflozin*), Glyxambi (*empagliflozin* and *linagliptin*) and Synjardy (*empagliflozin* and *metformin*), which are all indicated for only one use: lowering blood glucose in adults with type 2 diabetes.

78. SGLT2 inhibitors, including Farxiga and Xigduo XR, 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 due to their diabetes diagnoses.

79. Though Farxiga and Xigduo XR 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 Farxiga and Xigduo XR to both healthcare professionals and direct to consumers for off label purposes, including but not limited to weight loss, blood pressure reduction, and to treat Type 1 diabetics.

80. Upon information and belief, Plaintiffs' prescribing physicians and the Plaintiffs were marketed by Defendants through Defendant's sales representatives who visited the doctors' offices and through advertisement to promote Farxiga and/or Xigduo for off-label purposes, including weight loss and blood pressure reduction, and to treat Type 1 diabetics.

81. Upon information and belief, prescribing physicians were informed by Defendants that Farxiga and/or Xigduo XR could be used for off-label purposes as Defendants conducted clinical trials to specifically study weight loss, improvement of cholesterol in patients taking Farxiga, and treatment in Type 1 diabetics and the prescribing physicians were recruited to enroll patients in those trials and as a result become aware of the use of the medications for those non-approved indications .

82. In an effort to promote FARXIGA for off label purposes, Defendants conducted clinical trials to specifically study weight loss, improvement of cholesterol in patients taking FARXIGA, and the use of FARXIGA in Type 1 diabetic patients. A sampling of these studies include:

a. Does Dapagliflozin Promote Favorable Health Benefits That Are Independent Of Weight Loss?;

b. Exploratory Study to Investigate the Effect of Dapagliflozin and Exenatide Combined on Body Weight;

c. The Effects of Dapagliflozin on HDL Particles Subtypes and Reverse Cholesterol Transport in Type 2 Diabetic Patients;

d. Evaluation of the Effect of Dapagliflozin in Combination With Metformin on Body Weight in Subjects With Type 2 Diabetes

e. BMS – Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Dapagliflozin in Type 1 Diabetes.

83. Upon information and belief, Plaintiffs' prescribing physicians prescribed Farxiga to lower Plaintiff's blood sugar, assist in weight loss and/or blood pressure reduction, as a direct result of the representation of Defendant's marketing materials and/or sales representatives' statements.

84. Due to the concern over Defendants off-label promotions, consumer advocacy group, Public Citizen, sent a letter to the FDA on March 31, 2015 expressing their concerns over off-label promotional statements made by Defendants in direct-to-consumer advertising. Specifically, Public Citizen pointed out that advertisements for Farxiga containing statements related to (1) alleged weight-reducing properties, despite having no approval for such an indication and (2) alleged ability to reduce blood pressure, despite no approval for such an indication

85. In particular, some of the advertisements made the following statements "Farxiga may help you lose weight, and may even lower systolic blood pressure," "lose weight – on average 3%",[1] "significant weight reduction with 10mg dose,"[2] and "THE ONLY SGLT2

[1] https://www.ispot.tv/ad/A21Z/farxiga-everyday-people-song-by-sly-and-the-family-stone
[2] https://www.farxiga-hcp.com/efficacy/a1c-reductions.html

inhibitor with efficacy and safety data over 4 years; lowers A1c; with secondary benefit of weight loss."[3]

86. Additional off-label promotion language utilized by Defendants' sales representatives and in the marketing materials Defendants provide to doctors is not accessible to Plaintiffs without discovery on these issues.

87. In addition, any correspondence between the Defendants and FDA regarding off-label promotion is likewise not accessible to Plaintiffs without discovery on these issues.

Defendants' Duties Under the FDCA and State Law

88. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to prescription drugs rests with the NDA holders/drug sponsors (such as manufacturers and labelers) and their assigns or agents; they have a superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

89. To fulfill their essential responsibilities, these entities must vigilantly monitor all reasonably available information. They must closely evaluate the post-market clinical experience of their drugs and timely provide updated safety and efficacy information to the healthcare community and to consumers.

90. When monitoring and reporting adverse events, as required by both federal regulations and state law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to drug sponsors and the medical community that a public safety problem exists. If, for example, a manufacturer were to delay in reporting post-market information, that delay could mean that researchers, FDA, and the medical community are years behind in identifying a public safety issue associated with the

[3] https://plus.google.com/+AdpharmNet/posts/ANDQDgrFyFf

drug. In the meantime, more patients are harmed by using the product without knowing, understanding, or accepting its true risks. This is why drug sponsors must not only completely and accurately monitor, investigate and report post-market experiences, but they must also report the data in a timely fashion.

91. It is a central premise of federal drug regulation that the NDA holders and the assigns or agents –not the FDA-bear responsibility for the content of its label at all times. Consequently, NDA holders are primarily responsible for the crafting an adequate label and ensuring that warnings remain adequate as long as the drug is on the market.

92. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading, or does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacist sufficient information-including indications for use and "any relevant hazards, contraindications, side effects, and precautions-to allow those professionals "to use the drug safely and for the purpose for which it is intended." 21 C.F.R.. § 201.100(c)(1).

93. As part of their responsibility to monitor post-market clinical experiences with the drug and provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §

314.80(c)(1)(i-ii). Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually thereafter. 21 C.F.R. § 314.80 (c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.81(c)(2)(ii).

94. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

95. The "Changes Being Effected" (CBE) regulation, permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes "new analyses of previously submitted data." 21 C.F.R. § 314.3(b). Thus, for instance, if a drug sponsor were to determine that a warning were insufficient based on a new analysis of previously existing data, it could submit a CBE and change its labeling.

96. The longer the drug sponsor delays updating its labeling so that it reflects current safety information, the more likely it is that medical professionals will continue to prescribe drugs without advising patients of harmful side effect, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

Defendants Knew that Farxiga and Xigduo XR May Cause Diabetic Ketoacidosis and Severe Kidney Injury

97. Upon information and belief, Defendants knowledge of the risks of developing diabetic ketoacidosis and/or severe kidney injuries arose well before the FDA issued its first safety announcement regarding SGLT2 inhibitors in May of 2015.

98. Prior to Farxiga and Xigduo XR entering the US marketplace, Defendants were already selling dapagliflozin in other countries, including Australia, where *dapagliflozin* drugs are sold under the tradename Forxiga. On or about September 13, 2013, Defendants initiated a post-marketing evaluation of adverse events associated with *dapagliflozin*, entitled forREAL: Forxiga Prescription Event Monitoring Program (PEMP)(for REAL). The post-marketing evaluation study of the safety of Forxiga was to be conducted through an observational prescription adverse event monitoring program in Australia designed to study type 2 diabetes patients, newly prescribed Forxiga, to "assess real-world incidence of adverse events in routine clinical practice." Curiously, the study was terminated, citing lack of target recruitment not being met, and no data or results were reported. While no results were reported, Defendants indeed collected data from the start of the study through September 30, 2015.

99. Upon information and belief, since the occurrence of diabetic ketoacidosis and/or severe kidney injury associated with *dapagliflozin* containing drugs such as, Forxiga, Farxiga, and Xigduo XR, often occurs within a relatively short period of time after ingesting such products, it is likely that the data collected from this observational study (and other studies conducted by Defendants) contain reports of *dapagliflozin* associated diabetic ketoacidosis and/or severe kidney injury. However, further factual detail of the underlying data recorded in this study is impossible without additional discovery from Defendants.

100. Furthermore, Defendants commenced a study, entitled "Acute Kidney Injury in Patients on Dapagliflozin and Other Antidiabetic Medications," based on data collected as early as July 1, 2013, long before Plaintiffs ingested a dapagliflozin containing product, "to estimate the risk of hospitalization for acute kidney injury in patients who are prescribed dapagliflozin compared to patients prescribed other specific oral antidiabetic drugs." Defendants acknowledged in the study proposal that: "Because of the mechanism of action for dapagliflozin and results from small safety monitoring studies, there is an interest in further evaluating the safety of dapagliflozin in large populations. The study will be implemented in three administrative health care data sources in two countries: in the United Kingdom, the Clinical Practice Research Datalink (CPRD); and in the United States, the Centers for Medicare and Medicaid Services (CMS) Medicare databases and the HealthCore Integrated Research Database (HIRDSM). The study period starts July 1, 2013 in SPRD, January 1, 2014 in PHARMO and January 9, 2014 in the United States data sources, and will end at the latest available data at each database at the time of analysis." Thus, by Defendants own admission in this study proposal, enough data exists in small safety monitoring studies to warrant further evaluation of kidney injuries in patients taking *Dapagliflozin*. The results of these studies are not publicly available.

101. Although, Defendants have clearly recognized the need for adequate pharmacovigilence and proper post-market surveillance, an adequate post-marketing study has not been conducted to date. In addition, prior to the time Plaintiffs' were prescribed Farxiga and/or Xigduo XR, the Defendants were aware of numerous adverse event reports of DKA and severe kidney injury associated with the use of Farxiga and/or Xigduo XR.

102. Upon information and belief, as early as 2009, Defendants received adverse event reports during clinical trials, of patients on dapagliflozin, who developed diabetic ketoacidosis,

many of which were reported to the Defendants by the participating health care providers as being "related" to the patient's use of Farxiga. Defendants, on the other hand, almost always categorized these events as "unrelated." Adverse events of DKA continued to be reported to Defendants after Farxiga and Xigduo XR entered the US market. Defendants continued to overwhelming categorize these events as "unrelated."

103. Defendants were aware, or should have been aware, of the potential for Farxiga and Xigduo XR to cause kidney failure and/or acute kidney injury as early as 2012. An analysis of the medical review submitted with Invokana's NDA approval documents, which were publicly released nearly one year prior to Farxiga's own approval, disclosed a nearly three-fold increase (1.7% compared to 0.6%) in acute renal failure in patients taking high dose Invokana as compared to placebo, even in patients whose kidney function was considered normal at baseline.

104. Defendants knew that the likelihood of renal adverse effects such as acute renal failure was nearly tripled in patients with near normal kidney function taking a drug in the same class with a nearly identical mechanism of action and more than doubled in patients with even moderately impaired kidney function.

105. At the time of FDA Advisory Committee meeting, FDA renal review questioned Invokana's role in causing adverse events related to the kidneys, when it noted "the long term renal consequences of canagliflozin's effect on the eGFR are unknown.…It seems prudent to assume that the volume depletion and corresponding reduction in eGFR …places patients at increased risk for clinically significant episodes of acute kidney injury." The idea that Farxiga, a drug with the same mechanism of action and a substantially similar chemical makeup, could cause the same kinds of problems as Invokana should have occurred to a prudent pharmaceutical manufacturer.

106. The true extent of adverse event reports regarding the development of severe kidney injuries associated with the use of Farxiga and Xigduo XR cannot be plead with greater factual specificity without further discovery from Defendants. However, upon information and belief, Plaintiff asserts that Defendants knew or should have known of the risk of developing severe kidney injury associated with the use of Farxiga and/or Xigduo XR prior to Plaintiffs' ingestion of Xigduo XR and subsequent acute kidney injuries.

107. Upon information and belief, Defendants had actual knowledge of adverse events of diabetic ketoacidosis and acute kidney injury arising out of clinical trials and post-market surveillance which they did not accurately and/or timely report to the FDA.

108. When Defendants did report adverse events of diabetic ketoacidosis experienced by patients taking Farxiga and/or Xigduo XR to the FDA, Defendants misrepresented the nature of the adverse events to the FDA by:

a. describing reports of diabetic ketoacidosis for patients taking Farxiga and/or Xigduo XR as "unrelated" to the drug because, they claimed, diabetic ketoacidosis is a complication or risk of type 2 diabetes, however defendants failed to explain that diabetic ketoacidosis is exceedingly rare in type 2 diabetics;

b. blaming the diabetic ketoacidosis on the patient's non or poor compliance with their medications, despite the fact that the patient's non-compliance was so far removed in time so as to have no causal effect;

c. re-categorizing diabetic ketoacidosis as some other disorder (such as metabolic acidosis) in their reports to the FDA because the patient had "normal" blood sugars;

d. blaming the patient's other medical conditions as potentially causing diabetic ketoacidosis, despite the lack of any evidence of the other medical conditions' involvement (e.g., attributing diabetic ketoacidosis as potentially from a patient's history of alcoholism or pancreatitis without any evidence that alcoholism or pancreatitis were recent, ongoing, or in any way causal);

e. claiming that diabetic ketoacidosis can occur with patients with diabetes and uncontrolled blood sugars despite the absence of evidence of an uncontrolled blood sugar in that patient;

f. claiming that diabetic ketoacidosis is "not uncommon" in patients with Type 2 diabetes, when in fact it is exceedingly rare; and

g. claiming that "uncontrolled glycemia as evidenced by high urinary glucose was a significant risk factor for diabetic ketoacidosis," despite the fact that the mechanism of action of the drug results in a high urinary glucose for all patients and is not a reliable indicator of uncontrolled glycemia for patients on Farxiga and/or Xigduo XR.

109. Upon information and belief, Defendants would report adverse events of diabetic ketoacidosis by the symptoms of dehydration, nausea, vomiting, light headedness, volume depletion, or other such descriptions, while avoiding describing the adverse event as the serious diagnosis of ketoacidosis.

110. Upon information and belief, Defendants' sales representatives, pharmacovigilance department, and/or regulatory affairs department, would misrepresent,

withhold, or delay reporting adverse events of diabetic ketoacidosis to the FDA, despite the fact that this information was required to be reported to the FDA by federal law.

111. Upon information and belief, Defendants' sales representatives, pharmacovigilance department, and/or regulatory affairs department, would almost always categorize adverse events of diabetic ketoacidosis as "unrelated" to FARXIGA, even when the evidence suggested otherwise.

112. However, in at least one report of diabetic ketoacidosis and Farxiga on October 22, 2014, Defendants categorized DKA as causally related to Farxiga.

113. Upon information and belief, the adverse event reports of diabetic ketoacidosis were material and relevant to Farxiga's and/or Xigduo XR's performance, since these reports can often identify a signal or prompt a label change; a person taking Farxiga and/or Xigduo XR could develop diabetic ketoacidosis and the lack of inclusion of this side effect on the drug's label or in the Physician's Desk Reference could lead to a delayed or missed diagnosis of this potentially fatal side effect. If DKA is promptly diagnosed it can be treated and reversed. If it is not timely diagnosed, it can lead to coma, organ failure and death.

114. Upon information and belief, had Defendants accurately and timely reported adverse event reports of diabetic ketoacidosis and acute kidney injury to the FDA, the FDA could have required diabetic ketoacidosis and acute kidney injury to be included on the drug's original approval label, or have resulted in the FDA issuing its safety warning and subsequent label change earlier – prior to the time that Plaintiffs were first prescribed the drug. Had that occurred, Plaintiffs' physicians would not have prescribed Farxiga and/or Xigduo XR, and Plaintiffs would not have suffered the subsequent diabetic ketoacidosis and acute kidney injuries.

Similarly, even if the plaintiffs encountered those injuries, they could have been diagnosed sooner with less morbidity.

115. From March 2013 to June 6, 2014, the FDA received twenty (20) reports of DKA in patients treated with SGLT2 inhibitors. This data formed the basis of FDA's May 15, 2015 Safety Communication regarding SGLT2 inhibitors and their potential association with DKA. Upon information and belief, the Defendants knew or should have known of the potential association between Farxiga and/or XigduO XR and DKA and/or severe kidney injury prior to the FDA's initial safety announcement.

116. Likewise, from March 2013 to October 2015, FDA received reports of 101 confirmed cases of acute kidney injury, some requiring hospitalization and dialysis, associated with the use of Invokana, Invokamet, Farxiga, and Xigduo XR. The FDA linked approximately twenty-eight patients with acute kidney injury to the use of Farxiga alone. Upon information and belief, the defendants knew or should have known of the potential association between Farxiga and/or Xigduo XR and DKA and/or severe kidney injury prior to the FDA's initial safety announcement.

117. Furthermore, the data FDA used to issue its June 14, 2016 Safety Alert came from FDA Adverse Event Reporting System ("FAERS"), a publicly available database which Defendants, as manufacturers of a pharmaceutical drug submitted for approval and approved by FDA, is supposed to monitor for signals that the drug might be unsafe. The same kinds of signals that led FDA to issue its alert.

118. "The manufacturer of a pharmaceutical drug such as FARXIGA bears responsibility for the content of its label at all times. It is charged both with crafting an adequate

label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009).

119. As previously set forth in detail above, the Code of Federal Regulations ("CFRs") require manufacturers to alert FDA of potential risks and unequivocally place responsibility of monitoring the information to be included in the label at the manufacturer's doorstep. *See e.g.,* 21 CFR § 201.80(e) requires a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."; 21 CFR § 314.80(b) places responsibility for postmarketing surveillance on the manufacturer; and 73 Fed.Reg. 49605 says, "Manufacturers continue to have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information."

120. The entire set of information used by the FDA to change the Farxiga and Xigduo XR labels in December 2015 was available to Defendants prior to Plaintiffs' injuries.

121. The FDA, like all regulatory agencies, tracks adverse event data in FDA Adverse Event Reporting System ("FAERS").

122. The FAERS database established a clear signal that patients taking one of the SGLT-2 inhibitors, including Farxiga, are several times more likely to report ketoacidosis and/or acute kidney injury than those taking non-SGLT-2 diabetes drugs to treat type 2 diabetes.

123. The FAER's database is public and available to pharmaceutical manufacturers, meaning Defendants should have been aware of the signal prior to its decision to release Farxiga and/or Xigduo XR.

124. FDA guidelines for good pharmacovigilance practices require manufacturers to monitor the available data related to adverse events in the drug class, and specifically reference monitoring the FAERS database. "Additional cases could be identified from the sponsor's global

adverse event databases, the published literature, and other available databases, such as FDA's Adverse Event Reporting System (AERS)[.]"[4]

125. Even though the entire set of information FDA relied on to issue its May 15, 2015, December 4, 2015, and June 14, 2016 Safety Communication Letters were available to Defendants, Defendants did not warn Plaintiffs about the risks of DKA and acute kidney injury associated with Farxiga and/or Xigduo XR, until the FDA forced their hand.

126. Until the FDA required Defendants to change the Farxiga and/or Xigduo XR labels in December 2015, Defendants did not warn about Farxiga and/or Xigduo XR causing DKA. In fact, until December 2015 the Farxiga label did not contain any information about ketoacidosis, ketones, acidosis, DKA, or any information related to DKA on its label whatsoever.

127. However, Defendants were required by the European Medicines Agency (EMA) and other foreign regulatory bodies to warn healthcare providers of the serious risk of ketoacidosis associated with use of Farxiga and/or Xigduo XR .

128. On July 9, 2015, Defendants, in conjunction with other SGLT2 inhibitor manufacturers, issued a joint letter to healthcare professionals in Australia. The purpose of the letter was to warn doctors of new safety information related to SGLT2 inhibitors, including dapagliflozin products (Farxiga and Xigduo XR), of life-threating cases of DKA reported in association with the use of SGLT2 inhibitors. The letter also requested the physicians warn patients of the sign and symptoms of DKA when prescribing a SGLT2 inhibitor drug and to report adverse events.

[4] *FDA Guidance for Industry Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, p. 9, Final Version March 1, 2005, draft published May 4, 2004, available online at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf (last accessed January 31, 2017).

129. The following day, on July 10, 2015, Defendants, in conjunction with Janssen Pharmaceuticals (the makers of Invokana), issued a joint letter to healthcare professionals in Canada. The letter addressed a recent safety advisory issued by Health Canada on June 22, 2015 regarding a safety review investigation into whether Farxiga and Invokana were associated with DKA. Much like the Australian letter, the Canadian Dear Doctor Letter warned of the reporting of life-threating cases of DKA reported in association with the use of SGLT2 inhibitors. The letter also requested the physicians warn patients of the sign and symptoms of DKA when prescribing a SGLT2 inhibitor drug and to report adverse events.

130. On or about July 9, 2015, a similar Dear Healthcare Provider letter was issued in the United States, alerting healthcare providers of the FDA's recent May 15, 2015 Safety Communication. The letter cautioned that serious cases of DKA had been reported in patients taking SGLT2 inhibitors. However, Defendants failed to disclose the true risks of DKA associated with Farxiga and/or Xigduo XR or to update their labeling until the FDA required Defendants to change their labeling in December of 2015.

131. Furthermore, until the FDA required Defendants to change the Farxiga and/or Xigduo XR labels in June 2016, Defendants did not warn about Farxiga and/or Xigduo XR causing acute kidney injury. To date, Plaintiffs are unaware of any similar Dear Healthcare Professional letters issued by Defendants to warn of the serious risk of developing acute kidney injuries associated with Farxiga and/or Xigduo XR. Further factual detail cannot be alleged without additional discovery from the Defendants on such matters.

132. As part of their December 4, 2015 Safety Communication and label change, the FDA further required all manufacturers of SGLT2 inhibitors, including Defendants, to conduct a post-marketing study wherein the manufacturers would analyze spontaneous post-marketing

reports of ketoacidosis in patients treated with SGLT2 inhibitors, including specialized follow up to collect additional information, over a five (5) year period.

133. In 2013, prior to Plaintiffs' ingestion of Farxiga and/or Xigduo and prior to Plaintiffs' DKA and acute kidney injuries, a study was published which showed an increased risk of developing elevated blood ketone bodies for patients on the Farxiga competitor within the SGLT2 class, Invokana. N. Inagaki, K. Kondo, et al. *Efficacy and safety of canagliflozin in Japanese patients with type 2 diabetes: a randomized, double-blind, placebo-controlled, 12 week study.* 15 Diabetes, Obesity, and Metabolism 1135-1145 (2013).

134. In 2014, prior to numerous of the Plaintiffs' injuries, two more articles were published which associated SGLT2s with diabetic ketoacidosis:

a. Kelwade J, Sethi B, et al. *A case of "pseudo-ketoacidosis."* 18 Indian J. Endocrinol. Metab. 743 (2014).

b. Kaku K, Watade H, et al. *Efficacy and safety of monotherapy with the novel sodium/glucose contransporter-2 inhibitor tofogliflozin in Japanese patients with type 2 diabetes mellitus: a combined Phase 2 and 3 randomized, placebo-controlled, double-blind, parallel group comparative study.* 13 Cardiovascular Diabetology 2014.

135. Subsequently in 2015, multiple published case reports identified additional DKA and/or serious kidney injury events in patients treated with SGLT-2s. These reports include:

a. Hall, *Hall - 2015 -Case report of Ketoacidosis associated with Canagliflozin (Invokana).pdf*, March 5-8 ENDO CONFERENCE(2015).

b. Tomohide Hayami et al., *Case of ketoacidosis by a sodium-glucose cotransporter 2 inhibitor in a diabetic patient with a low-carbohydrate diet*, JOURNAL OF DIABETES INVESTIGATION n/a–n/a (2015).

c. Julia Hine et al., *SGLT inhibition and euglycaemic diabetic ketoacidosis*, THE LANCET DIABETES & ENDOCRINOLOGY (2015).

d. Nobuya Inagaki et al., *Efficacy and safety of canagliflozin alone or as add-on to other oral antihyperglycemic drugs in Japanese patients with type 2*

diabetes: A 52-week open-label study, 6 JOURNAL OF DIABETES INVESTIGATION 210–218 (2015).

e. Anne L. Peters et al., *Euglycemic Diabetic Ketoacidosis: A Potential Complication of Treatment With Sodium-Glucose Cotransporter 2 Inhibition*, DIABETES CARE dc150843 (2015).

f. Reginald St. Hilaire & Heather Costello, *Prescriber beware: report of adverse effect of sodium-glucose cotransporter 2 inhibitor use in a patient with contraindication*, 33 THE AMERICAN JOURNAL OF EMERGENCY MEDICINE 604.e3–604.e4 (2015).

g. Desai N. Erondu et al, *Diabetic Ketoacidosis and Related Events in the Canagliflozin type 2 Diabetes Clinical Program*, 38 DIABETES CARE (9), 1680-6 (Sept. 2015).

136. In addition, a letter to the editor published in the New England Journal of Medicine on June 8, 2017 describes a large scale study conducted by researchers at Brigham and Women's Hospital in Boston. They examined an insurance claim database, from which they identified 50,220 patients who had recently started a new prescription for an SGLT2 inhibitor, and compared them to a group of 90, 132 patients who had recently started a new prescription for a DPP4 inhibitor (another drug for type 2 diabetes). The study concluded that "SGLT2 inhibitors were associated with approximately twice the risk or diabetic ketoacidosis as were DPP4 inhibitors." Fralick M, Schneeweiss S, et al. *Risk of Diabetic Ketoacidosis after Initiation of an SGLT2 Inhibitor*. 376 N ENGL J MED 2300 (June 8, 2017).

137. Upon information and belief, Defendants' conduct regular literature searches to keep apprised of medical literature relating to their drugs. The above mentioned articles were therefore likely known to Defendants through this literature search process. Regular literature searches are a standard part of pharmaceutical pharmacovigilance programs.

138. Furthermore, as required by "Post-Marketing Surveillance to Evaluate the Safety and Efficacy of Forxiga in Patients With Type 2 Diabetes in Korea," Defendants had data available since November 2013 to evaluate incidents of diabetic ketoacidosis and acute kidney

injury and were required to conduct post-market surveillance. "This surveillance is a postmarketing commitment following the marketing authorization for Forxiga (dapagliflozin) in accordance with Standards on Re-examination of New Drugs, notified by the MFDS under Article 32, Paragraph 1 and Article 37, Paragraph 3 of Pharmaceutical Affairs Law. MFDS requires that at least 3,000 patients who can be evaluated for safety assessment should be collected within 6 years from 26 Nov 2013 to 25 Nov 2019."

139. Indeed, a study was published by the National Institute of Health entitled "Ketoacidosis and SGLT2 inhibitor treatment: Analysis of FAERS data by Blau et. al " that reflected 49 cases of Ketoacidosis and also 16 cases of acidosis from the time period of March 2013 through May 2015. Defendants had access to the data received by the FDA FAERS data and were thus on actual and certainly constructive notice of these serious events reported amongst patients taking Farxiga.

Defendants Acts and Omissions Are the Direct and Proximate Cause of Plaintiffs' Harm

140. Despite Defendants' knowledge of the increased risk of severe injury among users of Farxiga and Xigduo XR, they did not warn patients, such as the Plaintiffs, but instead continued to defend Farxiga and Xigduo XR, mislead physicians and the public, and minimized unfavorable findings.

141. Consumers, including Plaintiffs, who have used Farxiga and/or Xigduo XR for treatment of diabetes, have several alternative safer products available to treat type 2 diabetes.

142. Defendants knew of the significant risk of diabetic ketoacidosis and acute kidney injury caused by ingestion of Farxiga and Xigduo XR. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiffs, or the medical community of the severity of such risks.

143. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote Farxiga and Xigduo XR, and they willfully deceived Plaintiffs, Plaintiffs' health care professionals, the medical community, and the general public as to the health risks and consequences of the use of Farxiga and/or Xigduo XR.

144. As a direct result of Defendants' above described conduct, Plaintiffs were prescribed and began taking Farxiga and/or Xigduo XR for the treatment of diabetes.

145. Plaintiff John Grogan was first prescribed Farxiga on or about July 3, 2014.

146. Plaintiffs ingested and used Farxiga and/or Xigduo XR as prescribed by their physicians and in a foreseeable manner.

147. The Farxiga and/or Xigduo XR ingested by Plaintiffs was provided in a condition substantially the same as the condition in which they were manufactured and sold. Furthermore, at the time Plaintiffs ingested Farxiga and/or Xigduo XR, Defendants knew or should have known, of the increased risk for the development of diabetic ketoacidosis and severe kidney injuries, including acute kidney injury, associated with such use.

148. Plaintiffs agreed to initiate treatment with Farxiga and/or Xigduo XR in an effort to reduce blood sugar and hemoglobin A1c levels, reduce blood pressure, and/or lose weight. In doing so, Plaintiffs relied on claims made by Defendants that Farxiga and/or Xigduo XR were safe and effective for the treatment of diabetes, blood pressure reduction and/or weight loss.

149. Instead, Farxiga and/or Xigduo XR can cause severe injuries, including diabetic ketoacidosis and acute kidney failure.

150. After beginning treatment with Farxiga and/or Xigduo, and as a direct and proximate result thereof, on or about January 25, 2016 Plaintiffs suffered serious and potentially life-threating injuries including, but not limited to, DKA and/or acute kidney injury.

151. Defendants knew or should have known the risks associated with using Farxiga and/or Xigduo XR, *dapagliflozin* containing products, including the risk of developing diabetic ketoacidosis and acute kidney failure, prior to Plaintiffs' use of the Farxiga and/or Xigduo XR.

152. Despite Defendants superior knowledge of the true risks posed by the use of Farxiga and/or Xigduo XR, Defendants did not warn about the risks of DKA and/or kidney injury prior to Plaintiffs ingesting Farxiga and/or Xigduo XR.

153. Farxiga's and Xigduo XR's warnings were defective and/or unreasonably dangerous with regard to the increased risk of exposure to DKA and/or severe kidney injury.

154. The warnings were defective and/or unreasonably dangerous in that there simply were no warnings for DKA in the label for Farxiga and/or Xigduo XR at any time prior to December 4, 2015, despite information being available to Defendants prior to Plaintiffs' injuries that linked Farxiga, Xigduo XR, and other SGLT2 inhibitors to significantly increasing the risk of causing DKA.

155. Furthermore, the warnings were defective and/or unreasonably dangerous in that there simply were no warnings for acute kidney injury in the label for Farxiga and/or Xigduo XR at any time prior to June of 2016, despite information being available to Defendants prior to Plaintiffs' injuries that linked Farxiga, Xigduo XR, and other SGLT2 inhibitors to significantly increasing the risk of causing acute kidney injury.

156. The development of Plaintiffs' 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 Farxiga and/or Xigduo XR. Both

Defendants' conduct and the marketing and promotional defects complained of herein were substantial factors in bringing about and exacerbating Plaintiffs' injuries.

157. Plaintiffs' injuries were a reasonably foreseeable consequence of Defendants' conduct.

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

159. Plaintiffs would not have used Farxiga and/or Xigduo XR had Defendants properly disclosed the risks associated with its drugs. Thus, had the Defendants properly disclosed the risks associated with Farxiga and Xigduo XR, Plaintiffs would have avoided the risk of developing the injuries complained of herein, namely DKA and acute kidney injury, by not ingesting Farxiga and/or Xigduo XR.

160. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' physicians the true and significant risks associated with taking Farxiga and/or Xigduo XR.

161. Had Plaintiffs or their physicians received a proper or adequate warning as to the risks associated with FARXIGA and/or XIGDUO, the physicians would have provided Plaintiffs with adequate warnings and monitored urine for ketones and conducted testing to detect signs of DKA and acute kidney injury.

162. DKA almost invariably occurs in patients with Type I diabetes and is exceedingly rare in patients with Type II diabetes. A striking pattern was discerned by the FDA and should have been discerned by Defendants that DKA was observed in Type II Diabetics taking SGLT2

Inhibitors. Moreover, the typical presentation of a Type I diabetic with DKA was a patient appearing in the emergency room with very high glucose levels (hyperglycemic). What was notable in many of the DKA cases in patients taking SGLT2 inhibitors, including Farxiga, is that the patients presented as eucglycemic, with normal level of sugar in the blood. Thus internists, family doctors and emergency room doctors did not appreciate that the patients were presenting with DKA, and thus were not alerted to the necessary emergency treatment to provide to treat DKA and were not alerted to the need to immediately discontinue the use of Farxiga. This delayed diagnosis resulted in delayed treatment and thus worsened injuries.

163. As a result of Defendants' actions, Plaintiffs and Plaintiffs' prescribing physicians and treating doctors in the emergency rooms were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiffs 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. As a direct and proximate result of Defendants' negligence, wrongful conduct, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have 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. Plaintiffs seek actual and compensatory damages from Defendants.

Case Specific Facts

164. Plaintiff John Grogan was diagnosed with Type 2 Diabetes in 2011

165. On or about July 3, 2014, John Grogan was prescribed, and began using Farxiga as intended.

166. Defendants had a duty to warn prescribing physicians about the risks of DKA and/or severe kidney injury associated with their products.

167. Plaintiff John Grogan's physician would not have prescribed Farxiga to Mr. Grogan had he been advised of the risk of DKA and/or severe kidney injury associated with Farxiga.

168. On January 25, 2016 John Grogan presented to the Hendricks Regional Hospital where he was hospitalized and diagnosed with DKA and/or severe kidney injury.

169. As a direct result of Defendants' conduct and his use of Farxiga, John Grogan was injured and sustained damages, and will continue to do so in the future, including but not limited to: physical injury and harm, loss of life's pleasures, economic loss, impairment of future income, loss of earnings, past, present, and future medical expenses.

COUNT I
Strict Products Liability – Failure to Warn – Against All Defendants

170. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

171. Defendants, at all relevant times, have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Farxiga and/or Xigduo XR. Through that conduct, Defendants knowingly and intentionally placed Farxiga and/or Xigduo XR into the stream of commerce with full knowledge that it would reach consumers, such as Plaintiffs, who ingested the drugs.

172. Defendants, at all relevant times, researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Farxiga and/or Xigduo XR into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Farxiga and/or Xigduo XR to health care professionals, Plaintiffs, and other consumers, and therefore had a duty to warn of the risks associated with the use of Farxiga and/or Xigduo XR.

173. Defendants expected Farxiga and/or Xigduo XR to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiffs and Plaintiffs'

prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by the defendants.

174. Farxiga and/or Xigduo XR, as supplied by Defendants, failed to provide adequate warnings or instructions of the risks of side effects associated with the use of Farxiga and/or Xigduo XR, particularly the risks of developing DKA and/or acute kidney injury. 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, necessary medical monitoring and essential emergency signs for prompt diagnosis and treatment. As set forth in detail above, the Defendants knew or should have known of the risks, namely DKA and acute kidney injury, associated with the use of Farxiga and/or Xigduo XR.

175. The risks of developing DKA and/or acute kidney injury were known to or reasonably scientifically knowable by Defendants at the time Farxiga and/or Xigduo XR left Defendants' control, entered the stream of commerce, and were ingested by Plaintiffs.

176. Farxiga and/or Xigduo XR were defective and unsafe such that they were unreasonably dangerous when they left Defendants' possession and/or control, were distributed by the defendants, and when ingested by Plaintiffs. Farxiga and/or Xigduo XR contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with Farxiga and/or Xigduo XR, including the development of Plaintiffs' injuries, namely DKA and/or acute kidney injury.

177. Any warnings actually provided by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing DKA and/or acute kidney injury nor the need for monitoring of ketones and other clinical signs and the features that treating doctors should be aware of for

prompt diagnosis and treatment.

178. Without adequate warning of these side effects, Farxiga and/or Xigduo XR are not reasonably fit, suitable, or safe for their reasonably anticipated or intended purposes.

179. At all relevant times hereto, Plaintiffs used Farxiga and/or Xigduo XR in a foreseeable manner, as prescribed by their physicians, and for the reasonably intended use, for the treatment of diabetes, weight loss, and/or blood pressure reduction, in a reasonably anticipated manner.

180. Defendants knew or should have known, that use of Farxiga and/or Xigduo XR for its intended use, to treat diabetes, and for off-label use, carried with it unreasonably dangerous risks, namely the increased risks for developing DKA and/or severe acute kidney injury, prior to Plaintiffs' ingestion of Farxiga and/or Xigduo XR, as set forth above.

181. As a result of using Farxiga and/or XIGDUO XR, for its intended use or for off-label use, in a reasonably anticipated manner, Plaintiffs suffered severe injuries, namely DKA and/or acute kidney injury which diagnosis and treatment was delayed due to the inadequate warnings.

182. Had Plaintiffs been aware of the risks of DKA and acute kidney injury associated with the use of Farxiga and/or Xigduo XR they would not have used the drugs, and/or at a minimum, prescribing doctors would have been more alert to monitor and warn patients for the impending symptoms, and the emergency medical providers would have been able to more promptly diagnosis and treat the Plaintiffs.

183. 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 Farxiga and/or Xigduo XR did not cause users to suffer from unreasonable and dangerous risks.

184. Defendants negligently and recklessly marketed, labeled, distributed, and promoted Farxiga and/or Xigduo XR.

185. Defendants had a continuing duty to warn Plaintiffs and Plaintiffs' healthcare providers of the dangers associated with Farxiga and/or Xigduo XR.

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

187. In light of the episodes of DKA and acute kidney injury in Defendants' clinical trials involving dapagliflozin, published literature documenting increased ketones and acute kidney injury (renal failure) with SGLT2 inhibitors, and post-marketing surveillance reports of patients on Farxiga, Xigduo XR, and other SGLT2 inhibitors experiencing DKA and acute kidney injury, Defendants knew, or should have known, of the risk of DKA and acute kidney injury associated with Farxiga and/or Xigduo XR, prior to Plaintiffs first use of the drug.

188. Despite this knowledge, Defendants did not include DKA and/or acute kidney injury on the original approval label, nor did they voluntarily change the label on the drug to add these side effects, even though they had the authority to do so.

189. Instead, Defendants did not change the label until after the FDA required the changes to be implemented.

190. Upon information and belief, Defendants did not include any warning of the risk of DKA in any marketing materials utilized in the United States until after the December 2015 required label change. Additional discovery from the Defendants is required to provide further factual detail.

191. Likewise, upon information and belief, Defendants did not include any warning of the risk of acute kidney injury in any marketing materials utilized in the United States until after the June 2016 required label change. Additional discovery from the Defendants is required to

provide further factual detail.

192. Plaintiffs could not have discovered any defects in Farxiga and/or Xigduo XR through the exercise of reasonable care, and instead, Plaintiffs relied upon the skill, superior knowledge, and judgment of Defendants.

193. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that the Defendants knew or should have known that Farxiga and/or Xigduo XR 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 Farxiga and/or Xigduo XR, 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 product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

194. Farxiga and/or Xigduo XR, as supplied by Defendants, respectively, was unreasonably dangerous when used by consumers, including Plaintiffs, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

195. Each of the defendants knew or should have known that the limited warnings disseminated with Farxiga and/or Xigduo XR 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. Despite having superior knowledge of the risks associated with the foreseeable use of Farxiga and/or Xigduo XR to treat type 2 diabetes, weight loss, and/or blood

pressure reduction, namely the risks of developing DKA or acute kidney injuries, the Defendants failed to warn consumers, such as the Plaintiffs of such risks.

196. Rather, 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 Farxiga and/or Xigduo XR 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 FARXIGA and/or XIGDUO XR;

b. continued to aggressively promote FARXIGA and/or XIGDUO XR even after Defendants knew or should have known of the unreasonable risks from use as set forth above herein;

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 FARXIGA and/or XIGDUO XR 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 FARXIGA's and/or XIGDUO XR's effect on renal function and propensity to cause ketoacidosis as set forth above herein;

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 FARXIGA and/or XIGDUO XR as set forth above herein.

197. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Farxiga and/or Xigduo XR.

198. Due to these deficiencies and inadequacies, Farxiga and/or Xigduo XR was unreasonably dangerous and defective as advertised, sold, labeled, and marketed by Defendants, respectively.

199. Had Defendants properly disclosed and disseminated the risks associated with Farxiga and/or Xigduo XR, Plaintiffs would have avoided the risk of developing the injuries alleged herein by electing not to ingest Farxiga and/or Xigduo XR.

200. Had Defendants included the risk of DKA and acute kidney injury in the original or subsequent labels, Plaintiffs would not have been prescribed and therefore would not have taken Farxiga and/or Xigduo XR.

201. If Plaintiffs had not been prescribed Farxiga and/or Xigduo XR, Plaintiffs would not have suffered and developed DKA and/or acute kidney injury.

202. 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 Farxiga and/or Xigduo XR and the risks associated with such usage.

203. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered diabetic ketoacidosis and/or acute kidney injuries, and/or other related health complications.

204. In addition, as a result of the injuries caused by Defendants, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have 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. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and

all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT II
Negligence

205. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

206. Defendants directly or indirectly caused Farxiga and/or Xigduo XR, to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiffs.

207. Defendants owed Plaintiffs and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Farxiga and Xigduo XR, 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 Plaintiffs and other consumers of the dangers associated with Farxiga and Xigduo XR.

208. 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 associated with the use of Farxiga and Xigduo XR. Specifically, as alleged above, Defendants knew or should have known of the risks of DKA and severe acute kidney injury associated with the use of Farxiga and/or Xigduo XR prior to Plaintiffs' ingestion of Farxiga and/or Xigduo XR and subsequent injury/ies.

209. Defendants had a duty to disclose to health care professionals the causal relationship or association of Farxiga and Xigduo XR to the development of Plaintiffs' injuries.

210. 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 Farxiga and/or Xigduo XR, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of Farxiga and/or Xigduo XR, including the injuries suffered by

Plaintiffs.

211. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold Farxiga and/or Xigduo XR, they knew, or in the exercise of reasonable care should have known, that their products were defective, dangerous, and otherwise harmful to Plaintiffs as described above herein.

212. Defendants knew, or in the exercise of reasonable care should have known, that the use of Farxiga and/or Xigduo XR could cause or be associated with Plaintiffs' injuries, namely the development of DKA and/or acute kidney injury, and thus created a dangerous and unreasonable risk of injury to users of the products.

213. Defendants knew that many health care professionals were prescribing Farxiga and/or Xigduo XR, and that many patients developed serious side effects including but not limited to diabetic ketoacidosis and severe kidney injuries.

214. Defendants knew that emergency medical providers would not promptly diagnose DKA amongst Type II diabetics who do not present with DKA under ordinary cirumstances, and or who do not present with eucglycemic glucose levels but in DKA, resulting in delayed treatment and thus putting Plaintiffs at enhanced risk of grave sequellae of DKA.

215. Despite this knowledge, as outlined herein, Defendants did not include any warnings of the risk of DKA and/or acute kidney injury associated with Farxiga and/or Xigduo XR in its warning labels, television advertising, marketing materials, or sales representative statement to doctors. Instead, the messaging was that Farxiga and/or Xigduo XR were safe and effective, would lower a patient's A1C level, cause the patient to lose weight, and lower the patient's blood pressure.

216. 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 Farxiga and/or Xigduo XR in interstate commerce, in that the defendants knew and had reason to know that a consumer's use and ingestion of Farxiga and/or Xigduo XR created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiffs' injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

217. Defendants were further negligent in that they manufactured and produced a defective product containing *dapagliflozin*, and *dapagliflozin propanediol*, respectively, and they knew and were aware of the defects inherent in their products, 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.

218. 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 Farxiga and/or Xigduo before releasing the drugs to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Farxiga and/or Xigduo;

c. failing to conduct sufficient post-market testing and surveillance of Farxiga and/or Xigduo XR;

d. designing, manufacturing, marketing, advertising, distributing, and selling Farxiga and/or Xigduo XR 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 Farxiga and/or Xigduo XR 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 Farxiga's and Xigdou XR'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 adequate warn treating emergency personnel and family doctors and internists of the risks and the need to discontinue the use of the medications;

i. failing to exercise due care when advertising and promoting Farxiga and/or Xigduo XR; and

j. negligently continuing to manufacture, market, advertise, and distribute Farxiga and/or Xigduo XR after they knew or should have known of their adverse effects.

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

220. Defendants negligently and carelessly breached this duty of care to Plaintiffs because Farxiga and/or Xigduo XR were and are unreasonably defective in design as follows:

a. Farxiga and/or Xigduo XR unreasonably increase the risks of developing Plaintiff's injuries as complained of herein, specifically it increases the risk of developing DKA (Fralick M, Schneeweiss S, et al. *Risk of Diabetic Ketoacidosis after Initiation of an SGLT2 Inhibitor*. 376 N ENGL J MED 2300 (June 8, 2017));

b. Farxiga and/or Xigduo XR are not reasonably safe as intended to be used;

c. Farxiga and/or Xigduo XR are more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. Farxiga and/or Xigduo XR 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. Farxiga and/or Xigduo XR were not safe for its intended use;

f. Farxiga and/or Xigduo XR were not adequately tested;

g. Farxiga's and/or Xigduo XR's risks exceeded any benefit of the drugs;

h. Farxiga and/or Xigduo XR decrease the blood glucose levels so much that not enough insulin is produced (since insulin production is triggered by glucose levels) to prevent the body from metabolizing fat (lipolysis), which leads to a release of ketones;

i. Farxiga and/or Xigduo XR lead to an increase of glucagon, which stimulates lipolysis and ketones are released;

j. Farxiga's and/or Xigduo XR's mechanism of action (preventing absorption of glucose in the proximal renal tubule and instead flushing the glucose out through urine) leads to dehydration and salt depletion, resulting in a lowering of blood pressure. When this occurs, the body reacts to maintain blood pressure by producing increased hormones designed to increase blood pressure (like cortisol, epinephrine, glucagon). The presence of these hormones can exaggerate ketogenesis; and/OR

k. Farxiga and/or Xigduo XR prevent the kidneys from excreting ketones in the urine, which results in a build up of ketones in the body and can result in a lack of ketones in the urine, even when a person is experiencing diabetic ketoacidosis.

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

222. Plaintiffs did not know the nature and extent of the injuries that could result from ingestion and use of Farxiga and/or Xigduo XR.

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

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

225. Defendants' Farxiga and/or Xigduo XR was 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.

226. At all times relevant hereto, Farxiga and/or Xigduo XR were manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which were dangerous for use by the public and in particular by Plaintiffs.

227. Plaintiffs used Farxiga and/or Xigduo XR for their intended purposes and in a manner normally intended: to treat type 2 diabetes, reduce blood pressure, and/or promote weigh loss.

228. The harm caused by Farxiga and/or Xigduo XR, namely Plaintiffs' development of DKA and/or acute kidney injury, far outweighed the benefits, rendering Farxiga and/or Xigduo XR 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 Farxiga and/or Xigduo XR, to make them less dangerous. When the defendants manufactured Farxiga and/or Xigduo XR, the state of the industry's scientific knowledge was such that a less risky design was attainable.

229. At the time Farxiga and/or Xigduo XR 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 Farxiga and/or Xigduo XR. This was demonstrated by the existence of other diabetes medications, such as sulfonylureas and DPP-4s, that had a more established safety profile and a considerably lower risk profile.

230. Within the SGLT2 class, Jardiance is an alternative safer product available to treat type 2 diabetes, in that studies have shown it is more effective in lowering A1C than Farxiga and/or Xigduo XR, is shown to result in a larger weight loss than Farxiga and/or Xigduo XR, and it has an FDA approved indication for reducing cardiovascular deaths.

231. Alternatively, if no reasonable safer alternative was available, Defendants should have chosen not manufacture and sell Farxiga and/or Xigduo XR.

232. Plaintiffs could not, in the reasonable exercise of care, have discovered the defects of Farxiga and/or Xigduo XR and perceived the danger.

233. The defects in Farxiga and/or Xigduo XR were substantial contributing factors in causing Plaintiffs' injuries. But for the defendants' acts and omissions, Plaintiffs would not have suffered the injuries complained of herein.

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

235. In addition, as a result of the injuries caused by Defendants, Plaintiffs require and will continue to require healthcare and services. Plaintiffs have 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. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering.

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

COUNT III
Loss of Consortium

236. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

237. At all times state herein, Plaintiffs' spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

238. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

239. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

240. For all Spouse Plaintiffs, Plaintiffs allege his/her martial relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

241. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

242. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Plaintiff Spouses and Family Member Plaintiffs have been deprived of love, companionship, comfort, affection, society, solace or moral support, protection, loss of

enjoyment of relationship with Plaintiffs and will continue to sustain damages. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray 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 plaintiffs' injury;

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

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

7. Attorneys' fees, expenses, and costs of this action; and

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

JURY DEMAND

Plaintiffs demand trial by jury on all issues.

Dated: January 25, 2018

Respectfully submitted,

/s/ Robert T. Dassow
Robert T. Dassow, #15145-64
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Attorney for Plaintiffs

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

John Grogan and Victoria Grogan 1:18-cv-00224

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Robert T. Dassow, HOVDE DASSOW & DEETS, LLC
10201 N. Illinois Street, Ste. 500
Indianapolis, IN 46290

DEFENDANTS

Bristol-Myers Squibb Co., et al.

County of Residence of First Listed Defendant New York
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 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	**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	☐ 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	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 **PROPERTY RIGHTS** ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 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	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 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

REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS
☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**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

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Sec. 1332

Brief description of cause:
Personal Injury-Product Liability actio between citizens of Indiana and a Delaware Corp.

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 _____ DOCKET NUMBER _____

DATE 01/25/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Robert T. Dassow

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

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

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

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

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

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

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

UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

JOHN GROGAN AND VICTORIA GROGAN

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB CO., ET AL.

Defendant(s)

Civil Action No. 1:18-cv-00224

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bristol-Myer Squibb Co.
345 Park Avenue
New York, New York 10154

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, Ste. 500
Indianapolis, IN 46290

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. 1:18-cv-00224

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

JOHN GROGAN AND VICTORIA GROGAN

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB CO., ET AL.

Defendant(s)

Civil Action No. 1:18-cv-00224

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AstraZeneca AB
1800 Concord Pike
Wilmington, DE 19803

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, Ste. 500
Indianapolis, IN 46290

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. 1:18-cv-00224

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

JOHN GROGAN AND VICTORIA GROGAN

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB CO., ET AL.

Defendant(s)

Civil Action No. 1:18-cv-00224

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AstraZeneca PLC
1800 Concord Pike
Wilmington, DE 19803

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, Ste. 500
Indianapolis, IN 46290

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. 1:18-cv-00224

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

JOHN GROGAN AND VICTORIA GROGAN

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB CO., ET AL.

Defendant(s)

Civil Action No. 1:18-cv-00224

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19803

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, Ste. 500
Indianapolis, IN 46290

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. 1:18-cv-00224

PROOF OF SERVICE

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_____ 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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Southern District of Indiana

JOHN GROGAN AND VICTORIA GROGAN

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB CO., ET AL.

Defendant(s)

Civil Action No. 1:18-cv-00224

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AstraZeneca LP
1800 Concord Pike
Wilmington, DE 19803

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, Ste. 500
Indianapolis, IN 46290

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CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No. 1:18-cv-00224

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❒ 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):*

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

Date: _____

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Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset