UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STEVE COLLINS,

Plaintiff,

COMPLAINT AND DEMAND FOR JURY TRIAL

Civil Case No.: 1:16-cv-09722

v.

BRISTOL-MYERS SQUIBB CO., ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP

Defendants.

CIVIL COMPLAINT

Plaintiff STEVE COLLINS, by and through their undersigned counsel, bring this action seeking judgment against BRISTOL-MYERS SQUIBB CO., ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP, (collectively, Defendants) for injuries and damages caused by Plaintiff's ingestion of FARXIGA, a type 2 diabetes drug in the *gliflozin* class. Plaintiff alleges that at all time hereinafter mentioned:

NATURE OF ACTION

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

2. Defendants concealed their knowledge of FARXIGA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

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

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

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

PARTIES

6. At all times relevant hereto, Plaintiff was a resident and citizen of Gresham, Oregon, located in Multnomah County.

7. Defendant 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 drug FARXIGA.

8. Defendant AstraZeneca LP is a Delaware corporation with its principal place of business at 1209 Orange Street, Wilmington, Delaware. AstraZeneca LP is a wholly owned subsidiary of defendant AstraZeneca PLC. 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 drug FARXIGA.

9. Defendant AstraZeneca Pharmaceuticals LP is a Delaware corporation with its principal place of business at 1209 Orange Street, Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of Defendant AstraZeneca PLC. 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 drug FARXIGA.

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

JURISDICTION AND VENUE

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

12. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including FARXIGA, within the States of Oregon and New York, with a reasonable expectation that the products would be used or consumed in these states, and thus regularly solicited or transacted business in these states.

13. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and misleading information about FARXIGA to consumers, including

Plaintiff, and to health care professionals in the States of Oregon, New York and throughout the country with a reasonable expectation that such information would be used and relied upon by consumers and health care professionals throughout the States of Oregon and New York and throughout the country.

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

15. 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 drug Farxiga, in the State of New York. As such, this Court has personal jurisdiction over all named defendants.

16. Venue of this case is proper in the Southern District of New York 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 Plaintiff's claims occurred in the Southern District of New York.

FACTUAL BACKGROUND

17. 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.

18. 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.

19. Five days later, on January 13, 2014 in another joint press release issued with both companies 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."

20. On Feb. 3, 2014, AstraZeneca announced that it completed the acquisition of Bristol-Myers Squibb's interests in the companies' "diabetes alliance." 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.

21. Defendants' acts in their corporate alliance to market and promote FARXIGA acts took place, in substantial part, in New York. Each Defendant has continuously and systematically entered into transactions, in this District and throughout the United States.

22. The clinical trials referenced in the press releases described above were conducted in numerous locations including the State and City of New York.

23. As a *gliflozin* drug, FARXIGA's active ingredient is *dapagliflozin propanediol*.

24. SGLT2 inhibitors, including FARXIGA, are indicated for only one use: lowering blood glucose in adults with type 2 diabetes.

25. SGLT2 inhibitors, including FARXIGA, 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.

26. Though FARXIGA is 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 to both healthcare professionals and direct to consumers for off label purposes, including but not limited to weight loss and reduced blood pressure.

27. Since FARXIGA's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of these drugs.

28. An analysis of the FDA adverse event database shows that patients taking one of the SGLT2 inhibitors, including FARXIGA, are twice as likely to report ketoacidosis and/or severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

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

30. Consumers, including Plaintiff, who have used FARXIGA for treatment of diabetes, have several alternative safer products available to treat the conditions.

31. Defendants knew of the significant risk of diabetic ketoacidosis and kidney damage caused by ingestion of FARXIGA. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity of such risks.

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

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

34. Plaintiff ingested and used FARXIGA as prescribed and in a foreseeable manner.

35. The FARXIGA used by Plaintiff was provided in a condition substantially the same as the condition in which it was manufactured and sold.

36. Plaintiff agreed to initiate treatment with FARXIGA in an effort to reduce blood sugar and hemoglobin A1c levels. In doing so, Plaintiff relied on claims made by Defendants that FARXIGA was safe and effective for the treatment of diabetes.

37. Instead, FARXIGA can cause severe injuries, including diabetic ketoacidosis, and acute kidney failure.

38. Plaintiff began taking FARXIGA on or about November 2014.

39. Plaintiff was prescribed, purchased, ingested, and exposed to FARXIGA in Multnomah County, Oregon. As a result of ingesting FARXIGA, Plaintiff suffered personal and

economic injuries, which developed and occurred in Mutnomah County, Oregon, and Plaintiff sought and received treatment for the effects attendant thereto.

40. While taking FARXIGA. Plaintiff experienced severe abdominal pain. nausea. and vomiting. Plaintiff went to Providence St. Vincent Medical Center in Portland, Oregon, and was admitted to the Intensive Care Unit where Plaintiff spent several days.

41. After beginning treatment with FARXIGA, and as a direct and proximate result thereof, Plaintiff suffered diabetic ketoacidosis and was admitted to Providence St. Vincent Medical Center on December 23, 2014.

42. Defendants knew or should have known the risks associated with using FARXIGA, including the risk of developing diabetic ketoacidosis and acute kidney failure.

43. Defendants did not warn about the risks of DKA prior to his suffering the diabetic ketoacidosis. Subsequent to his injury, the package insert was changed to warn of those risks.

44. While Defendants did not warn about the risks of DKA. on May 15, 2015, the FDA issued a safety announcement covering the SGLT2 inhibitor class, warning about the risk of diabetic ketoacidosis and advising that the FDA would continue to evaluate the safety issue.

45. On December 4, 2015, the FDA issued a 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."

46. In light of the data disclosed in the December 4, 2015 safety communication. the FDA changed the label for FARXIGA 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.

47. 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 postmarketing study wherein the manufacturers would analyze spontaneous postmarketing reports of ketoacidosis in patients treated with SGLT2 inhibitors, including specialized follow-up to collect additional information, over a 5-year period.

48. In 2015, multiple published case reports identified additional DKA 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 Kline 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).

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

50. FARXIGA by its very mechanism of action causes 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.

51. Because FARXIGA blocks 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.

52. 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.

53. 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, uncncumbered, may require kidney transplants.

54. FARXIGA causes osmotic diuresis due to its 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 makes kidney injury a higher likelihood, even for those with normal kidney function at the beginning of FARXIGA therapy.

55. On June 14, 2016, the FDA issued a drug safety communication about dapagliflozin, warning that FARXIGA can cause acute kidney injury. The drug safety communication linked 28

patients with acute kidney injury and use of FARXIGA, with hospitalization, intensive care unit admission, and death resulting from the injury in some cases.

56. Defendant was aware of the potential for FARXIGA and other drugs in the SGLT-2 inhibitor class to cause kidney failure prior to FARXIGA's approval. For example, Invokana's medical review, submitted with Invokana's NDA approval documents in 2012 and publicly released nearly a year before Farxiga was approved, disclosed a nearly three-fold increase (1.7% compared to 0.6%) in acute renal failure for patients taking the higher dose of Invokana compared to those taking placebo, even in patients whose kidney function was normal.

57. 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.

58. At the time of the FDA Advisory Committee meeting, the 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.

59. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful

misrepresentations concerning the nature and safety of FARXIGA. Both Defendants' conduct and the marketing and promotional defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's injuries.

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

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

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

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

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

65. As a direct and proximate result of Defendants' negligence, wrongful conduct, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured

pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from all Defendants.

COUNT I

PRODUCT LIABILITY – FAILURE TO WARN (STRICT LIABILITY)

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

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

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

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

70. FARXIGA, as supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks

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

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

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

73. 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 did not cause users to suffer from unreasonable and dangerous risks.

74. Defendants negligently and recklessly marketed, labeled, distributed, and promoted FARXIGA.

75. Defendants had a continuing duty to warn Plaintiff of the dangers associated with FARXIGA.

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

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

78. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that the defendants knew or should have known that FARXIGA 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, 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.

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

80. Each of the defendants knew or should have known that the limited warnings disseminated with FARXIGA 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.

81. 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 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;

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

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of FARXIGA 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 effect on renal function and propensity to cause ketoacidosis;

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

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

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

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

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

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

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

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

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

COUNT II

NEGLIGENCE

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

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

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

91. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of FARXIGA.

92. Defendants had a duty to disclose to health care professionals the causal relationship or association of FARXIGA to the development of Plaintiff's injuries.

93. 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 (2) appropriate, complete, and accurate warnings concerning the adverse effects of FARXIGA, including the injuries suffered by Plaintiff.

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

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

96. Defendants knew that many health care professionals were prescribing FARXIGA, and that numerous patients developed serious side effects including but not limited to diabetic ketoacidosis.

97. 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 in interstate commerce, in that the defendants knew and had reason to

know that a consumer's use and ingestion of FARXIGA created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

98. 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 product, failed to act in a reasonably prudent manner in designing, testing, and marketing their product, and failed to provide adequate warnings of their product's defects and risks.

99. 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 before releasing the drugs to market;

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

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

d. designing, manufacturing, marketing, advertising, distributing, and selling FARXIGA 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 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 effect on acid balance and renal function;

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

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

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

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

a. Defendants negligently and carelessly breached this duty of care to Plaintiff because FARXIGA was and is unreasonably defective in design as follows:

b. FARXIGA unreasonably increases the risks of developing Plaintiff's injuries as complained of herein;

c. FARXIGA was not reasonably safe as intended to be used;

d. FARXIGA are more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

e. FARXIGA 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;

f. FARXIGA was not safe for its intended use;

g. FARXIGA was not adequately tested; and/or

h. FARXIGA's risks exceeded any benefit of the drug.

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

102. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of FARXIGA.

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

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

105. Defendants' FARXIGA 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.

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

107. Plaintiff used FARXIGA for its intended purposes and in a manner normally intended: to treat diabetes.

108. The harm caused by FARXIGA far outweighed the benefits, rendering FARXIGA 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, to make them less dangerous. When the defendants manufactured FARXIGA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

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

110. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of FARXIGA and perceived the danger.

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

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

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

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

COUNT III

WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE

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

115. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that the defendants'

conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, the defendants' conduct involved an extreme degree of risk.

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

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

118. Plaintiff therefore asserts claims for exemplary damages.

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

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

adverse side effects of ingesting FARXIGA, despite their knowledge and awareness of these serious side effects and risks.

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

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

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

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

125. Defendants' acts, conduct, and omissions were willful and malicious. The defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other users of FARXIGA and for the primary purpose of increasing Defendants' profits from the sale and distribution of FARXIGA. Defendants'

outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all defendants in an amount appropriate to punish and make an example out of each.

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

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

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

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

PRAYER FOR RELIEF

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

1. Judgment in favor of Plaintiff and against all defendants, for damages in such amount as may be proven at trial;

2. Compensation for both economic and non-economic losses including but not limited to medical expenses, loss of earnings, loss of consortium, pain and suffering, mental anguish and emotional distress in such amounts as may be proven at trial

3. Punitive and/or exemplary damages;

4. Interest;

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

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

JURY TRIAL DEMAND

Plaintiff demands trial by jury.

Dated: December 16, 2016

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