

**IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

GARRET SCOTT, INDIVIDUALLY AND	)	
ON BEHALF OF LINDA ALEXIS WHITE,	)	
DECEASED,	)	17-MD-2776 (LGS)
	)	
Plaintiff,	)	CIVIL ACTION NO. 1:17-cv-7048
v.	)	
	)	COMPLAINT
	)	
BRISTOL-MYERS SQUIBB CO.;	)	JURY DEMANDED
ASTRAZENECA LP; and ASTRAZENECA	)	
PHARMACEUTICALS LP,	)	
	)	
Defendants.	)	

Plaintiff, Garret Scott, individually and on behalf of Linda Alexis, White, deceased, by and through his undersigned counsel, brings this action seeking judgment against Bristol-Myers Squibb (BMS) 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.

**INTRODUCTION**

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, and continue to conceal, their knowledge of FARXIGA’s unreasonably dangerous risks from Linda Alexis White, deceased, other consumers, and the medical community.

3. As a result of the risky nature of FARXIGA, persons who were prescribed and ingested FARXIGA, including Linda Alexis White, deceased, have suffered and may continue to suffer severe and permanent personal injuries, including death. Diabetic ketoacidosis is a serious and potentially life threatening complication of diabetes that occurs when your body produces high levels of blood acids called ketones.

4. After beginning treatment with FARXIGA, and as a direct and proximate result of Defendants' actions and inaction, Linda Alexis White, deceased, developed diabetic ketoacidosis, chronic kidney disease and end-stage renal disease which ultimately led to her death. Ms. White's ingestion of the unreasonably dangerous drug FARXIGA has caused and will continue to cause injury and damage to Linda Alexis White, deceased, and to Plaintiff Garret Scott.

5. Plaintiff brings this action for personal injuries suffered and the demise of Linda Alexis White as a proximate result of being prescribed and ingesting FARXIGA. Plaintiff accordingly seeks compensatory damages, monetary restitution, and all other available remedies as a result of Ms. White's injuries and death caused by FARXIGA.

### **PARTIES**

6. At all times relevant hereto, Linda Alexis White was a resident and citizen of Knoxville, Tennessee, located in Knox County, and was prescribed, purchased, ingested, and exposed to FARXIGA in Knox County, Tennessee. As a result of ingesting FARXIGA, Plaintiff suffered personal and economic injuries, which developed and occurred in Knox County, Tennessee, and Plaintiff sought and received treatment for the effects attendant thereto. As a direct and proximate result of ingesting FARXIGA, Linda Alexis White died of chronic kidney disease on September 17, 2016.

7. Plaintiff, Garret Scott, is an adult and citizen of the State of Tennessee, residing in Knox County.

8. 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.

9. 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.

10. 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.

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

**JURISDICTION AND VENUE**

12. 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.

13. 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 Tennessee 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.

14. 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 Tennessee, 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 State of Tennessee.

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

16. 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.

17. Defendant BMS' principal place of business is located at 345 Park Avenue, New York, New York.

18. Defendants, by its employees or agents attended meetings at BMS' corporate headquarters regarding the research and/or development, and/or FDA approval, and/or marketing of FARXIGA.

19. At all times relevant to this action, Defendants were joint venturers and worked together to achieve the common business purpose of selling FARXIGA.

20. 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**

21. 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.

22. 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.

23. 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.” 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.

24. Defendants' acts in their corporate alliance to market and promote FARXIGA 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. The clinical trials referenced in the press releases described above were conducted in numerous locations including the State and City of New York.

25. As a *gliflozin* drug, FARXIGA’s active ingredient is *dapagliflozin propanediol*.

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

27. 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.

28. 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.

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

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

31. 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.

32. Consumers, including Linda Alexis White, deceased, who have used FARXIGA for treatment of diabetes, have several alternative safer products available to treat and control their conditions.

33. 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 Linda Alexis White, deceased, or the medical community of the severity of such risks.

34. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote FARXIGA, and they willfully deceived Linda Alexis White, deceased,

her health care professionals, the medical community, and the general public as to the health risks and consequences of the use of FARXIGA.

35. As a direct result of Defendants' above described conduct, Linda Alexis White, deceased, was prescribed and began taking FARXIGA to treat type II diabetes.

36. Ms. White ingested and used FARXIGA as prescribed and in a foreseeable manner.

37. The FARXIGA used by Ms. White was provided in a condition substantially the same as the condition in which it was manufactured and sold.

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

39. Instead of safely treating Ms. White's diabetes, FARXIGA caused severe injuries, including diabetic ketoacidosis, chronic kidney disease, end-stage renal disease, and death.

40. Ms. White was prescribed, purchased, ingested, and exposed to FARXIGA in Knox County, Tennessee. As a result of ingesting FARXIGA, Linda Alexis White, deceased, suffered personal and economic injuries, which developed and occurred in Knox County, Tennessee and she sought and received treatment for the effects attendant thereto.

41. Linda Alexis White, deceased, began taking FARXIGA on or about January of 2014.

42. In 2016, initiating after treatment with FARXIGA, and as a direct and proximate result thereof, Plaintiff suffered diabetic ketoacidosis on or about February 4, 2016; acute renal failure on or about March 28, 2016; acute kidney injury on or about April 16, 2016; acute renal



failure on or about June 30, 2016; end-stage renal disease on or about July 26, 2016; and death due to chronic kidney injuries on September 17, 2016.

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

44. While Defendants did not warn about the risks of diabetic ketoacidosis (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. As part of their continued evaluation, on December 4, 2015, the FDA issued a new safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to diabetic 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 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 5-year period.

48. In 2015, multiple published case reports identified additional DKA events in patients treated with SGLT2s. 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).

49. Along with the above described ketone related injuries, SGLT2 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, unencumbered, 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. Defendants were aware of the potential for FARXIGA and other drugs in the SGLT2 inhibitor class to cause kidney failure prior to FARXIGA's approval. For example, Invokana's (SGLT2) 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 (Invokana'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 Ms. White's injuries and death 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 Ms. White's injuries and causing her death.

60. Linda Alexis White's injuries and death 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. Ms. White 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, she would have avoided the risk of developing the injuries and resulting death by not ingesting FARXIGA.

63. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Ms. White and her physicians the true and significant risks associated with taking FARXIGA.

64. As a result of Defendants' actions, Ms. White and her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that she 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, Linda Alexis White, deceased, suffered severe physical and emotional injuries. Ms. White endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment, and death. Plaintiff seeks actual and compensatory, 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 Linda Alexis White, deceased, 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, Ms. White, 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 Linda Alexis White, deceased, and her 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 Linda Alexis White, deceased. FARXIGA contained warnings insufficient to alert consumers, including Ms. White, to the dangerous risks and reactions associated with

FARXIGA, including the development of Ms. White's injuries and contributing factor to her death.

72. This defect caused serious injury to Linda Alexis White, deceased, 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 Ms. White 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. Linda Alexis White, deceased, could not have discovered any defects in FARXIGA through the exercise of reasonable care, and instead, Ms. White 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 Linda Alexis White, deceased, 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, Ms. White would have avoided the risk of developing the injuries alleged herein that led to her death.

85. Defendants are liable to Linda Alexis White, deceased, for injuries and death 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, Ms. White suffered diabetic ketoacidosis, chronic kidney injuries, end-stage renal disease, death, and other related health complications.

87. In addition, as a result of the injuries caused by Defendants, Linda Alexis White, deceased, required healthcare and services, incurred medical and related expenses, suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, premature death, and other losses and

damages. Linda Alexis White's direct medical losses and costs include physician care, monitoring, and treatment. Ms. White has incurred mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's 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. 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 Linda Alexis White, deceased.

90. Defendants owed Ms. White and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, 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 Ms. White 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 Linda Alexis White's injuries and death.

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 Linda Alexis White, deceased.

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 Linda Alexis White, deceased.

95. Defendants knew, or in the exercise of reasonable care should have known, that the use of FARXIGA could cause or be associated with Ms. White's injuries and death 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 Ms. White's injuries and death, 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 premarketing 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 Linda Alexis White, deceased, 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.

101. Defendants negligently and carelessly breached this duty of care to Linda Alexis White, deceased, because FARXIGA was and is unreasonably defective in design as follows:

a. FARXIGA unreasonably increases the risks of developing Ms. White's injuries and death as complained of herein;

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

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

d. FARXIGA contained insufficient, incorrect, and defective warnings in that they failed to alert health care professionals and users, including Linda Alexis White, deceased, of the severity of the risks of adverse effects;

e. FARXIGA was not safe for its intended use;

f. FARXIGA was not adequately tested; and/or g. FARXIGA's risks exceeded any benefit of the drug.

102. Defendants knew and/or should have known that it was foreseeable that consumers such as Linda Alexis White, deceased, would suffer injuries and death as a result of

the defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of FARXIGA.

103. Ms. White did not know the nature and extent of the injuries that could result from ingestion and use of FARXIGA.

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

105. Defendants' conduct, as described above, was reckless. The defendants' actions and inaction risked the lives of consumers and users of their product, including Linda Alexis White, deceased.

106. 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.

107. 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 Ms. White.

108. Ms. White used FARXIGA for its intended purposes and in a manner normally intended: to treat diabetes.

109. 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.

110. 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.

111. Linda Alexis White, deceased, could not, in the reasonable exercise of care, have discovered the defects of FARXIGA and perceived the danger.

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

113. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ms. White suffered diabetic ketoacidosis, chronic kidney injuries, end-stage renal disease, death, and other related health complications.

114. In addition, as a result of the injuries caused by Defendants, Ms. White required healthcare and services, incurred medical and related expenses, suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, premature death, and other losses and damages. Linda Alexis White's direct medical losses and costs include physician care, monitoring, and treatment. Ms. White has incurred 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**

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

116. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Linda Alexis White, deceased, in that the defendants' conduct was specifically intended to cause substantial injury to Ms. White. 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.

117. 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 Ms. White and her healthcare providers.

118. Linda Alexis White, deceased, relied on Defendants' representations and suffered injuries and death as a proximate result of this reliance.

119. Ms. White therefore asserts claims for exemplary damages.

120. Ms. White 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 her.



121. Linda Alexis White, deceased, 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 Linda Alexis White, deceased, 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.

122. 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.

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

124. 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.

125. 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 Linda Alexis White, deceased, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by FARXIGA.

126. 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 Ms. White 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.

127. 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 Ms. White. As such, Defendants unreasonably subjected consumers of FARXIGA to risk of injury.

128. 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 Ms. White, 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.

129. Defendants' conduct was committed with willful and conscious disregard for the safety of Ms. White, entitling her 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.

**COUNT IV**  
**FAILURE TO WARN UNDER THE COMMON LAW AND TENNESSEE**  
**PRODUCT LIABILITY ACT**

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

131. This claim is brought pursuant to the common law and the Tennessee Product Liability Act.

132. At the time of Linda Alexis White's injuries, Defendants did not warn, or in the alternative provided inadequate warnings to Ms. White and her treating physicians as to the risk that FARXIGA could cause diabetic ketoacidosis, renal injury, severe infection, or death.

133. The warnings that did accompany FARXIGA failed to provide that level of information that an ordinary consumer would expect when using FARXIGA.

134. Had Ms. White or her health care providers received a proper or adequate warning as to the risks associated with taking FARXIGA, she would not have used FARXIGA.

135. Had Ms. White or her physicians received proper or adequate warnings, they would not have recommended FARXIGA, or at a minimum, provided Ms. White with adequate warning and obtained her informed consent.

136. The failure to warn of the risks of FARXIGA caused serious damage and contributed to Linda Alexis White's death

**COUNT V**  
**WRONGFUL DEATH**

137. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

138. Plaintiff brings this claim, where appropriate, on behalf of the Estate and for the benefit of the Linda Alexis White's lawful beneficiaries.

139. As a direct and proximate result of the conduct of the Defendants and the defective nature of FARXIGA as outlined above, Linda Alexis White suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

140. As a direct and proximate cause of the conduct of Defendants, Linda Alexis White's beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiff brings this claim on behalf of Linda Alexis White's lawful beneficiaries for these damages and for all pecuniary losses sustained.

**COUNT VI**  
**SURVIVAL ACTION**

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

142. As a direct and proximate result of the conduct of Defendants, where appropriate, Linda Alexis White, prior to her death, was obligated to spend various sums of money to treat her injuries, which debts have been assumed by the Estate. As a direct and proximate cause of the aforesaid, Ms. White suffered a loss of earnings and earning capacity. Plaintiff brings this claim on behalf of Linda Alexis White's estate under applicable state statutory and/or common laws.

143. As a direct and proximate result of the conduct of Defendants, Linda Alexis White and her spouse, until the time of her death, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

144. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Linda Alexis White until the date of her death, Plaintiff has suffered and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Garret Scott, as Administrator or beneficiary of the estate of the Linda Alexis White, brings the claim on behalf of the estate for damages under applicable statutory and/or common laws, and in their own right.

**PRAYER FOR RELIEF**

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

1. For general damages in a sum in excess of the jurisdictional minimum of this court;
2. For consequential damages in excess of the jurisdictional minimum of this Court;
3. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of \$75,000;
4. Medical expenses and other economic damages in an amount to be determined at trial of this action;
5. Pain and suffering;
6. Non-economic damages;
7. Prejudgment interest at the highest lawful rate allowed by law;
8. Interest on the judgment at the highest legal rate from the date of judgment until collected;
9. Attorneys' fees, expenses, and costs of this action; and
10. Such further relief as this Court deems necessary, just and proper.

**JURY DEMAND**

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal rules of Civil Procedure and the Seventh Amendment to the U.S. Constitution on all issues within this Petition.

Respectfully submitted,

**Dated:** September 15, 2017

**MILSTEIN, JACKSON, FAIRCHILD &  
WADE, LLP**

/s/Levi M. Plesset \_\_\_\_\_  
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