IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

ADELINA QUINTANILLA, *Plaintiff*, vs. BRISTOL-MYERS SQUIBB CO., a Delaware corporation, Serve: The Corporation Trust Company Corp. Trust Center 1209 Orange St. Wilmington, DE 19801 and ASTRAZENECA LP, a Delaware corporation Serve: The Corporation Trust Company Corp. Trust Center 1209 Orange St. Wilmington, DE 19801 and ASTRAZENECA PHARMACEUTICALS LP, a Delaware corporation Serve: The Corporation Trust Company Corp. Trust Center 1209 Orange St. Wilmington, DE 19801 *Defendants.*	) Case No. 2:16-cv-00172) COMPLAINT) JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Adelina Quintanilla, (Plaintiff), by and through her undersigned counsel, brings this action seeking judgment against Bristol-Myers Squibb Co., AstraZeneca LP, and AstraZeneca Pharmaceuticals LP, (collectively referred to as 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 Plaintiff, other consumers, and the medical community.

3. As a result of the defective 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 stroke, heart attack, 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 defective and unreasonably dangerous drug has caused and will continue to cause injury and damage to Plaintiff.

5. This is an action for product liability, failure to warn, strict liability, and negligence against BRISTOL-MYERS SQUIBB CO. (BMS), ASTRAZENECA LP, and ASTRAZENECA PHARMACEUTICALS LP.

6. 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, monetary restitution, and all other available remedies as a result of injuries caused by these medications.

PARTIES

8. At all times relevant hereto, Plaintiff Adelina Quintanilla was a resident and citizen of Corpus Christi, Texas, located in Nueces County, and was prescribed, purchased, ingested, and exposed to FARXIGA in Nueces County, Texas. As a result of ingesting FARXIGA, Plaintiff suffered personal and economic injuries, which developed and occurred in Nueces County, Texas, and she sought treatment for the effects attendant thereto.

9. 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.

10. 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.

11. 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.

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

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 State of Texas, with a reasonable expectation that such information would be used and relied upon by consumers and health care professionals throughout the State of Texas.

15. Defendants engaged in substantial business activities in the State of Texas. At all relevant times, Defendants transacted, solicited, and conducted business in Texas through their

employees, agents, and/or sales representatives and derived substantial revenue from such business in Texas.

16. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Texas. As such, this Court has personal jurisdiction over all named defendants.

17. Venue of this case is proper in the Southern District of Texas pursuant to 28 U.S.C. § 1391(b)(1) because Plaintiff was injured in this District.

18. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the Southern District of Texas.

FACTUAL BACKGROUND

19. 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 (Sodium Glucose Cotransporter 2) inhibitors.

20. SGLT2 inhibitors, including FARXIGA, are indicated for only lowering blood glucose in type 2 diabetics.

21. 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.

31. Defendants are responsible for designing, developing, manufacturing, marketing, distributing, selling and otherwise introducing FARXIGA into the stream of commerce. As a *gliflozin* drug, FARXIGA's active ingredient is *dapagliflozin propanediol*.

32. Though FARXIGA is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market FARXIGA for off label purposes, including but not limited to weight loss and reduced blood pressure.

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

34. 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.

35. 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.

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

37. 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.

38. 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.

39. As a direct result of Defendants' above described conduct, in or about May 2014, Plaintiff was prescribed and began taking FARXIGA to treat diabetes.

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

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

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

43. Instead, FARXIGA can cause severe injuries, including diabetic ketoacidosis.

44. After beginning treatment with FARXIGA, and as a direct and proximate result thereof, Plaintiff suffered ketoacidosis.

45. Defendants knew or should have known the risks associated with using FARXIGA, including the risk of developing diabetic ketoacidosis.

46. On May 15, 2015, the FDA issued a safety announcement regarding the entire SGLT2 inhibitor class warning about the risk of diabetic ketoacidosis.

47. 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 product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's injuries.

48. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and FARXIGA's defects.

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

50. 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 those medications.

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

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

53. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of FARXIGA, 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 both Defendants.

54. Plaintiff has suffered from mental anguish from the knowledge that she may suffer life-long complications as a result of the injuries caused by FARXIGA.

COUNT I
PRODUCT LIABILITY – DESIGN DEFECT (STRICT LIABILITY)

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

56. Defendants, respectively, designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed FARXIGA, FARXIGA, used by Plaintiff, which were in a defective and unreasonably dangerous condition.

57. Defendants expected FARXIGA to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by Defendants.

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

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

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

b. When placed in the stream of commerce, FARXIGA was defective in design and formulation, making use of the drugs more dangerous than an

ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes;

c. FARXIGA was insufficiently tested;

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

e. Defendants were aware at the time FARXIGA was marketed that ingestion of FARXIGA would result in an increased risk of diabetic ketoacidosis and other injuries;

f. Inadequate post-marketing surveillance; and/or

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

60. FARXIGA was defective, failed to perform safely, and were unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

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

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

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

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

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

66. Plaintiff was prescribed, purchased, and used FARXIGA. Plaintiff used this drug for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants, respectively.

67. Neither Plaintiff nor Plaintiff's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with FARXIGA before Plaintiff's ingestion of FARXIGA.

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

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

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.

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

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

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

73. Due to the unreasonably dangerous condition of FARXIGA, Defendants are liable for Plaintiff's injuries.

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

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

76. 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
PRODUCTS LIABILITY – FAILURE TO WARN (STRICT LIABILITY)

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

78. 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 them.

79. 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.

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

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

82. FARXIGA was defective and unsafe such that they were unreasonably dangerous when they left Defendants' possession and/or control, were distributed by the defendants, and 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.

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

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

85. Defendants negligently and recklessly labeled, distributed, and promoted FARXIGA.

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

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

88. 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.

89. 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 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.

90. FARXIGA, as manufactured and/or 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.

91. Each of the defendants knew or should have known that the limited warnings disseminated with FARXIGA was inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the 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.

92. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drugs safely for use by patients for the purposes for which they are 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.

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

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

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

96. 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 with its use.

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

98. 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

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

100. 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.

101. 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.

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

103. Plaintiff therefore asserts claims for exemplary damages.

104. 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.

105. 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 those medications, despite their knowledge and awareness of these serious side effects and risks.

106. 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.

107. 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.

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

109. 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.

110. 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.

111. 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.

112. 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.

113. 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.

COUNT IV
NEGLIGENCE

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

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

116. Defendants owed Plaintiff 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 Plaintiff and other consumers of the dangers associated with FARXIGA.

117. 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.

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

119. 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.

120. 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.

121. 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.

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

123. 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.

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

125. 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.

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

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

a. FARXIGA unreasonably increases the risks of developing Plaintiff's injuries 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 Plaintiff, 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.

128. 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.

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

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

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

132. 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.

133. 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.

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

135. 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.

136. 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.

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

138. 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.

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

140. 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.

PRAYER FOR RELIEF

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

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering;

4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;

5. Punitive damages;

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

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

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

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

JURY DEMAND

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

Dated: May 23, 2016

Respectfully submitted,

PHIPPS ANDERSON DEACON LLP

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Trial Counsel for Plaintiff
**motion for pro hac vice admission forthcoming*

JS 44 (Rev. 11/15)

CIVIL COVER SHEET

Case No. 2:16-cv-00172

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

I. (a) PLAINTIFFS

Adelina Quintanilla

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Martin Phipps, Phipps Anderson Deacon LLP, The Pipps, 102 9th Street, San Antonio, TX 79215 (210) 340-9877

DEFENDANTS

Bristol-Myers Squibb Co., Astrazeneca LP, and Astrazeneca Pharmaceuticals LP

County of Residence of First Listed Defendant Manhattan, NY
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

Brief description of cause:
pharmaceutical products liability action regarding Defendants' drug, Farxiga

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 05/23/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ James R. Holstein

FOR OFFICE USE ONLY

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