In the United States District Court
Southern District of Texas
Houston Division

Michael Bustamante	§	**C.A. No. _____**
	§	
vs.	§	
	§	
AstraZeneca AB and AstraZeneca Pharmaceuticals LP	§	
	§	

Plaintiff' ORIGINAL COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW the Plaintiff Michael Bustamante ("Plaintiff"), by and through Plaintiff' undersigned attorneys, and file this, Plaintiff' Original Complaint and Demand for Jury Trial against Defendants AstraZeneca AB and AstraZeneca Pharmaceuticals LP, (collectively "Defendants"), and allege as follows:

PARTIES

1. Plaintiff Michael Bustamante resides in Deer Park, Texas. Plaintiff Michael Bustamante was prescribed and used Farxiga and was damaged thereby.
2. Defendant AstraZeneca AB is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Sodertalje, Sweden. AstraZeneca AB is the holder of the New Drug Application for Farxiga. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca AB manufactures, markets, distributes and sells Farxiga throughout the United States.
3. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike,

Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP, which does business as AstraZeneca US) is a subsidiary of AstraZeneca AB. AstraZeneca Pharmaceuticals LP is listed as the distributor of Farxiga on the Farxiga label. Accordingly, AstraZeneca Pharmaceuticals LP is a citizen of Delaware. AstraZeneca Pharmaceuticals LP may be served with process by serving its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

4. At all times relevant to this Complaint, AstraZeneca AB and AstraZeneca Pharmaceuticals LP were each, individually and in concert with one another, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, advertising, promoting, marketing, and introducing into interstate commerce, either directly or indirectly through third-parties or related entities, its products, including the prescription drug that is the subject of this lawsuit, Farxiga.

JURISDICTION AND VENUE

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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 ALLEGATIONS

Development and Approval of Farxiga

12. Farxiga is an oral Type 2 diabetes medication. It is part of the gliflozin drug class that is referred to generally as sodium-glucose cotransporter 2 (SGLT2) inhibitors. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. SGLT2 inhibitors,

such as Farxiga, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. SGLT-2 inhibitors reduce blood sugar levels by reducing glucose reabsorption through the user's kidneys and increasing glucose excretion in the user's urine.

13. The first SGLT2 inhibitor drug to come to market in the United States was Invokana (canagliflozin) in March of 2013. Janssen Pharmaceuticals, Inc. opened an Investigational New Drug Application for Invokana on May 25, 2007. Five years later, on May 31, 2012, Janssen submitted a New Drug Application ("NDA") for Invokana. The FDA approved Invokana on or about March 29, 2013.

14. During a similar time period, Bristol-Myers Squibb was working to bring Farxiga (capagliflozin) to market. Bristol-Myers Squibb ("BMS") submitted a New Drug Application for Farxiga on or about December 28, 2010.

15. Upon reviewing the data contained in Bristol-Myers Squibb's initial submission, the FDA found that the data did not support the conclusion that the benefits of Farxiga outweighed the drug's risks. As a result, the FDA issued a Complete Response Letter on January 17, 2012, regarding its concerns which included: risk of liver injury, cancer risks, cardiovascular risks, lack of efficacy in some patients. Although BMS filed a Formal Dispute Resolution Request of the FDA ruling, the appeal was denied by the FDA in September of 2012.

16. On or about July 11, 2013, BMS re-submitted a new NDA for Farxiga, seeking an indication for the use of Farxiga to improve glycemic control in adult patients with Type 2 diabetes. 19. On October 29, 2013, AstraZeneca AB submitted an NDA for Xigduo XR – which is dapagliflozin combined with metformin HCI extended-release, again seeking an indication for use to improve glycemic control in adult patients with Type 2 diabetes.

17. On January 8, 2014, AstraZeneca and Bristol-Myers Squibb issued a press release (noting prominently on their New York stock exchange ticker), stating that they had formed an "alliance" and had 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, it was announced that AstraZeneca would acquire Bristol-Myers Squibb's interest in the companies' diabetes alliance.

18. Finally, on January 8, 2014, the FDA approved FARXIGA (dapagliflozin) for use in treatment of Type 2 diabetics.

Farxiga's Association with Necrotizing Fasciitis Of The Genital/Perianal/Gluteal Regions (Including Fournier's Gangrene).

19. SGLT2 inhibitors, including Farxiga, are indicated for only one use: glycemic control in Type 2 adult diabetics. Nevertheless, to increase market share, Defendants 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.

20. Prior to the introduction of SGLT2 inhibitors, Fournier's gangrene was exceedingly rare. A study looking at data from 2001 and 2004 concluded that the overall incidence rate of Fournier's gangrene was 1.6/100,000 men.

21. Since Farxiga's release, the FDA has received a significant number of reports of adverse events, including: necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), ketoacidosis, severe kidney disease and lower limb amputations.

22. With regard to Fournier's gangrene, a form of necrotizing fasciitis of the genital/perianal/gluteal regions, the FDA has observed that an increased incidence of Fournier's gangrene had been reported in patients taking SGLT2 inhibitors. From March 2013 to May 2018, the FDA identified twelve cases of Fournier's gangrene in patients taking an SGLT2 inhibitor such as Farxiga. By comparison, only six cases of Fournier's gangrene were identified by the FDA in a review of other antidiabetic drug classes over a period exceeding three decades. The FDA noted that additional cases of Fournier's gangrene likely existed.

23. Specifically, Defendants knew or should have known of the risks of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) based on basic principles of infectious disease science and data available to it or that could have been generated by it, including, but not limited to, animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports, and regulatory authority investigations, as follows:

- Farxiga's selectivity for the SGLT1 receptor;
- Animal studies demonstrating an increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) when given Farxiga;
- Clinical and post-clinical studies demonstrating increases in risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) in people taking Farxiga;
- Clinical and post-clinical studies, adverse event reports, and case reports demonstrating increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) in people taking Farxiga;

- Adverse event report analysis demonstrating an increased rate of reports for necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) for people taking Farxiga;
- The increased incidence and risks of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) reflected in animal studies, clinical and post clinical studies, adverse event reports, case reports, medical literature and other sources examining other SGLT2 inhibitors such as Farxiga; and
- The basics of infectious disease science.

24. Defendants also knew or should have known that the mechanism of action for Farxiga causes an extraordinary risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) among Farxiga users.

Defendants' Failures to Properly Design Farxiga and Warn About Farxiga's Risks

25. Despite their knowledge of data indicating that Farxiga use is associated with and/or causally related to necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), Defendants: (a) promoted and marketed Farxiga as safe and effective for persons such as Plaintiff throughout the United States; (b) did not warn patients about the increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene); (c) did not alert consumers and physicians about the monitoring required to ensure the safety of patients taking Farxiga; (d) continued to defend Farxiga against claims that it caused necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene); (e) minimized unfavorable findings; and (f) did not conduct the necessary additional studies to properly evaluate this risk prior to marketing the drug to the general public.

26. Defendants conducted nationwide sales and marketing campaigns to promote Farxiga, and they willfully deceived Plaintiff and Plaintiff' doctors, the medical community, and the general public as to the health risks and consequences of using Farxiga.

27. Defendants published advertisements on their company websites and issued press releases announcing information about Farxiga. These announcements did not contain warnings about necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) and/or the increased risk of those conditions caused by Farxiga.

28. To the best of Plaintiff' knowledge, prior to the time of Plaintiff's diagnosis, all marketing materials, advertisements, press releases, web site publications, "Dear Doctor" letters, and other communications regarding Farxiga that were put forth by Defendants omitted any mention of the increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) caused by Farxiga.

29. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Farxiga, both as to its ability to lower glucose, and its benefit for non-surrogate measures of health, such as reducing adverse cardiovascular outcomes. Defendants misrepresented that Farxiga is a safe and effective treatment for Type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including, but not limited to, necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene).

30. Notably, at the time of Mr. Bustamante's diagnosis, information concerning the association between Farxiga and necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) was not publicly available.

31. Consumers of Farxiga and their prescribing physicians relied on Defendants' false representations and were misled as to the drug's safety, and, as a result, have suffered injuries including necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) and the life-threatening complications thereof.

32. Although Defendants had a duty to warn Mr. Bustamante's prescribing physicians about the risks of Farxiga use, including the risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), Defendants through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with taking Farxiga.

33. At all times herein mentioned, the officers and directors of Defendants' participated in, authorized, and directed the production and promotion of Farxiga when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product.

Plaintiff's Injuries

34. Consumers, including Plaintiff, Michael Bustamante, who have used Farxiga for treatment of Type 2 diabetes, weight loss and/or reduced blood pressure, have several safer alternative products available to treat these conditions.

35. Yet, as a direct result of Defendants' conduct, Mr. Bustamante was prescribed Farxiga by his treating physician and began taking Farxiga on or about _____2018. Plaintiff ingested and used Farxiga as prescribed by his doctor and in a foreseeable manner until on

or about_____. The Farxiga used by Plaintiff was provided in a condition which was the same or substantially the same as the condition in which it was manufactured, sold and distributed by Defendants.

36. Plaintiff agreed to initiate treatment with Farxiga in an effort to treat Plaintiff's Type 2 diabetes. In doing so, Plaintiff relied on claims made by Defendants that Farxiga was safe and effective for the treatment of diabetes. Had Plaintiff and Plaintiff's physician(s) known the true risks associated with the use of SGLT2 inhibitors, including Farxiga, Plaintiff would not have been prescribed Farxiga, and Plaintiff would have refused to take Farxiga. Additionally, and alternatively, at a minimum, Plaintiff would have been adequately monitored for side effects from Farxiga, and as a result, would not have suffered injuries and damages from using Farxiga.

37. Plaintiff's prescribing and treating physician(s) relied on representations made by Defendants that Farxiga has been clinically shown to improve glycemic control and was generally safe and effective. These representations reached Plaintiff's prescribing and treating physician(s) directly, through print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' representations through their comprehensive marketing campaigns.

38. After beginning treatment with Farxiga, and as a direct and proximate result thereof, Plaintiff required extensive medical treatment and suffered debilitating injuries, including, but not limited to, destruction of critical tissue and bodily structures, necrotizing fasciitis of the perineum and genital region, and other injuries the full extent of which are not yet realized.

39. Due to Defendants' wrongful acts, omissions, and misrepresentations, Plaintiff endured severe and permanent physical injuries, pain and suffering, emotional distress, embarrassment, loss of consortium, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment that will continue in the future.

40. Plaintiff's injuries were 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 warnings, and willful misrepresentations concerning the nature and safety of Farxiga. This conduct and the product defects complained of brought about and/or were substantial factors in bringing about and exacerbating Plaintiff's injuries.

FDA's Safety Communication About Farxiga And The Risk Of Necrotizing Fasciitis Of The Genital/Perianal/Gluteal Regions (Including Fournier's Gangrene).

41. On August 29, 2018, the FDA issued a drug safety communication about the link between Fournier's gangrene and SGLT-2 inhibitors like Farxiga.

42. The FDA required that a new warning about the risk of necrotizing fasciitis of the perineum (Fournier's gangrene) be added to the labeling for Farxiga and other SGLT2 inhibitors. The FDA observed that cases of Fournier's gangrene had been reported in patients taking SGLT2 inhibitors. From March 2013 to May 2018, the FDA identified twelve cases of Fournier's gangrene in patients taking an SGLT2 inhibitor such as Farxiga. By comparison, only six cases of Fournier's gangrene were identified by the FDA in a review of other

antidiabetic drug classes over a period exceeding three decades. The FDA noted that additional cases of Fournier's gangrene likely existed.

43. Prior to the FDA's August 29, 2018 safety announcement, Farxiga's labeling failed to warn prescribing physicians and patients of the serious risk of necrotizing fasciitis of the genital/perianal/gluteal regions or Fournier's gangrene.

44. The prescribing information for Farxiga was subsequently changed on or about October 26, 2018, to include a warning for Fournier's gangrene. The label does not warn of the severity, frequency or duration of injuries associated with necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene). The current labeling does not warn that a patient might lose part of his or her genitals. Thus, Defendants continue to fail to ensure that full and correct labeling and warnings were and/or are used in materials provided to prescribing physicians.

FRAUDULENT CONCEALMENT

45. Defendants are estopped from relying on any statute of limitations defense because they failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of Farxiga. There was no way, at the time Mr. Bustamante was diagnosed, that Plaintiff, with exercise of ordinary diligence, could have discovered that Plaintiff' injuries might be related to the Farxiga Mr. Bustamante had ingested. Thus, under the applicable discovery rule, Plaintiff' cause of action did not accrue, and the statute of limitations did not begin to run, until Plaintiff knew, or in the exercise of ordinary diligence, should have known of the injury and the cause thereof.

46. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when Defendants had a duty to disclose those facts. Defendants kept Plaintiff ignorant of vital information essential to the pursuit of claims by Plaintiff without any fault or lack of diligence on the part of Plaintiff, for the purpose of obtaining delay in filing of Plaintiff' causes of action. Defendants' fraudulent concealment resulted in such delay.

47. Defendants are, and were, under a continuing duty to disclose that Farxiga is associated with a significant number of reports of adverse events, including necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), ketoacidosis, severe kidney disease and lower limb amputations, but instead they concealed them. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE LIABILITY, VICARIOUS LIABILITY AND AGENCY

48. At all times herein mentioned, the officers and/or directors of Defendants participated in, authorized and/or directed the production and promotion of Farxiga when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said product, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

49. Upon information and belief, Defendants were each the agent, servant, partner, and/or joint venturer of the other. Defendants were, at all relevant times, operating and acting within the

purpose and scope of said agency, service, employment, partnership, and/or joint venture and rendered substantial assistance and encouragement to the other knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

50. Defendants are liable for the acts of their agents to the extent that Defendants delegated, authorized, and ratified another to act on their behalf in furtherance of their objectives relating to the development, design, manufacture, marketing, labeling, promotion and sales of Farxiga.

51. Defendants, individually and acting in concert with one another, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by or for Plaintiff, including Farxiga.

CAUSES OF ACTION

COUNT ONE NEGLIGENCE

52. Plaintiff repeat and re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length herein, in its entirety.

53. At all times relevant to this cause of action, Defendants were in the business of designing, developing, manufacturing, compounding, marketing, promoting, labeling and selling medicinal drugs, including Farxiga.

54. At all times relevant hereto, Defendants were under a duty to act reasonably and use reasonable care to properly design, develop, manufacture, compound, market, promote, label

and sell a product that did not present a risk of harm or injury to Plaintiff and to those people receiving Farxiga. Defendants had a duty to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to consumers and users and to warn Plaintiff and other consumers and their physicians of the dangers associated with Farxiga. Defendants negligently and/or recklessly failed in these regards and their failures resulted in injuries and damages to Plaintiff.

55. At the time of manufacture, compounding, marketing and sale of Farxiga, Defendants knew or reasonably should have known that Farxiga was designed, compounded and manufactured in such a manner so as to present an unreasonable risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), ketoacidosis, severe kidney disease and lower limb amputations. Despite this knowledge, Defendants committed one or more breaches of their duty of reasonable care and were negligent and/or reckless in:

- Failing to properly and thoroughly test Farxiga before releasing the drug to market;
- Failing to properly and thoroughly analyze the data resulting from the pre- marketing tests of Farxiga;
- Failing to conduct sufficient post-market testing and surveillance of Farxiga;
- Designing, compounding, manufacturing, 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;
- Failing to disclose to health care professionals the causal relationship and/or association of Farxiga to adverse health conditions including necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failing to accompany their product with proper and/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;
- 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 necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

- Failing to fully and accurately disclose the clinical safety and effectiveness profile of Farxiga;
- Failing to exercise due care when advertising and promoting Farxiga; and
- Negligently continuing to manufacture, market, advertise and distribute Farxiga after they knew or should have known of the adverse effects of the medication.

56. Defendants negligently, carelessly and recklessly breached their duty of care to Plaintiff because

- Farxiga was and is unreasonably defective in design as follows:
- Farxiga unreasonably increased the risks of developing Plaintiff' injuries as complained of herein;
- Farxiga was not reasonably safe for its intended use;
- Farxiga is more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with products that treat Mr. Bustamante's condition;
- Farxiga was not adequately tested;
- Farxiga's risks exceeded the benefit of the drug; and
- Farxiga contained insufficient, incorrect and defective warnings in that they failed to alert health care professionals and users, including Plaintiff, of the full range, extent, severity and duration of the risks posed by Farxiga.

57. 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' failures to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of Farxiga.

58. Plaintiff and Plaintiff's doctors did not know the nature and extent of the injuries that could result from ingestion and use of Farxiga.

59. Farxiga was expected to and did reach consumers such as Plaintiff without any or any substantial change in the condition in which it was sold and without any or any substantial

change to the warnings at the time in which it was sold. The Farxiga ingested by Mr. Bustamante was in the same condition as when it was manufactured, compounded, inspected, marketed, labeled, promoted, distributed and sold by Defendants. Plaintiff Michael Bustamante used Farxiga for its intended purpose and in a manner normally intended.

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

61. 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.

62. As a direct and proximate result of Defendants' foregoing negligent, careless and reckless conduct, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against all Defendants jointly, severally and individually for all special and general damages, including pain and suffering, punitive damages and the costs of

this action, plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT TWO

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

63. Plaintiff re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

64. At all times relevant to this Complaint, the Defendants designed, manufactured, distributed, marketed, advertised, promoted and sold Farxiga.

65. Defendants impliedly represented and warranted to healthcare professionals and consumers (such as Plaintiff) that Farxiga was safe and effective for the particular purpose for which Farxiga was to be used. These aforementioned representations and warranties were false, misleading, and inaccurate because Farxiga was unsafe, ineffective, and caused harm to Plaintiff' health.

66. The injuries suffered by Plaintiff were proximately caused by the warranty breaches of Defendants, their agents, employees and/or servants in that:

- Defendants are merchants with respect to Farxiga;
- Defendants sold Farxiga in a defective, unsafe and inherently dangerous condition;
- Farxiga was expected to, and did reach users, handlers, and persons coming into contact with said products (including Plaintiff) without substantial change in the condition in which they were sold;
- Farxiga was not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made by Defendants; and

- Plaintiff, Michael Bustamante is a natural person who would have been reasonably expected to use, consume or be affected by Farxiga and was injured by the breach of this implied warranty.

67. Plaintiff reasonably relied on the implied warranty of merchantability provided by Defendants. Plaintiff reasonably relied upon the skill and judgment of Defendants with respect to whether Farxiga was safe and fit for its intended use.

68. By selling Plaintiff, Michael Bustamante, and his healthcare providers a defective and dangerous drug product, Defendants, individually and through their agents, employees, and/or servants, breached the implied warranty of merchantability provisions as set forth in the Uniform Commercial Code of this State and/or any applicable state.

69. As a direct and proximate result of Defendants' foregoing breaches of the aforementioned implied warranty, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses and consequential damages, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against all Defendants jointly, severally and individually for all special and general damages, including pain and suffering, damages caused by the breach of implied warranty of merchantability and the costs of this action plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT THREE

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

70. Plaintiff re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

71. The aforementioned incident was proximately caused by the actions and/or inactions of Defendants, their agents, employees and/or servants in that:

- Defendants had reason to know of the particular purpose for which Farxiga was intended;
- Defendants had reason to know that healthcare professionals and consumers buying Farxiga relied upon Defendants' skill and expertise in designing, manufacturing, labeling and selling a safe and effective pharmaceutical product when prescribing and ingesting Farxiga for the treatment of diabetes;
- Plaintiff is a natural person who would have been reasonably expected to use, consume or be affected by Farxiga and was injured by the breach of this implied warranty; and
- Plaintiff was relying on Defendants' skill or judgment to furnish a suitable product.

72. Plaintiff, Michael Bustamante, and his healthcare providers relied upon Defendants' skill and judgment to furnish suitable goods for the treatment of Plaintiff's diabetes. By selling to Plaintiff a defective drug product in the form of Farxiga, Defendants, individually and through their agents, employees, and/or servants, breached the implied warranty of fitness for a particular purpose provisions as set forth in as set forth in the Uniform Commercial Code of this State and/or any applicable state.

73. As a direct and proximate result of Defendants' foregoing breaches of the aforementioned implied warranty, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses and other consequential damages, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against all Defendants jointly, severally and individually for all special and general damages, including pain and suffering, damages caused by the breach of

warranty of fitness for a particular purpose and the costs of this action plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT FOUR

BREACH OF EXPRESS WARRANTY

74. Plaintiff re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

75. Defendants expressly warranted that Farxiga was safe for its intended use, effective as a treatment for diabetes, and as otherwise described in this Complaint. Farxiga did not conform to these express representations, including, but not limited to, the representation that Farxiga was safe and effective and the representation that Farxiga did not have high and/or unacceptable levels of side effects.

76. The express warranties made by the Defendants were a part of the basis for Mr. Bustamante's use of Farxiga, and Plaintiff's health care providers relied on Defendants' warranties in deciding to prescribe and use Farxiga.

77. At the time of making the express warranties, Defendants had knowledge of the purpose for which Farxiga was to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

78. Farxiga did not, and does not, conform to Defendants' express representations and description of the goods because Farxiga is not safe or effective and produces serious side effects, including necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene).

79. By making affirmations of fact regarding the safety and efficacy of Farxiga and by describing Farxiga as safe and effective such that Mr. Bustamante and his healthcare providers relied upon such affirmations and descriptions as a part of the basis of the bargain, an express warranty was created that Farxiga should conform to the affirmations and descriptions made by Defendants. Defendants, individually and through their agents, employees, and/or servants, breached the express warranty provisions as set forth in the Uniform Commercial Code provisions of this state and/or any applicable state.

80. As a direct and proximate result of Defendants' foregoing breaches of the aforementioned implied warranty, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses and other consequential damages, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against all Defendants jointly, severally and individually for all special and general damages, including pain and suffering, damages caused by the breach of express warranty and all other warranties described herein, and the costs of this action, plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT FIVE

STRICT PRODUCT LIABILITY – FAILURE TO WARN

81. Plaintiff repeat and re-allege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

82. Defendants designed, developed, set specifications, researched, tested, licensed, manufactured, prepared, compounded, assembled, processed, marketed, packaged, labeled,

promoted, distributed, and sold Farxiga in an unreasonably dangerous condition, including the Farxiga used by Plaintiff, Michael Bustamante.

83. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the drug into the stream of commerce, Defendants knew or should have known the drug was defective and presented an unreasonable danger to users when ingested for its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time that Farxiga was manufactured, labeled, distributed, sold and ingested by Mr. Bustamante, that the drug posed a significant risk of serious injuries, including, but not limited to, necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene). Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the drug.

84. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of Farxiga. No patient or healthcare provider (including Plaintiff and Plaintiff's healthcare providers) would have used the drug in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the drug. Therefore, the drug was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions.

85. Farxiga was expected to and did reach consumers such as Plaintiff without any or any substantial change in the condition in which it was sold and without any or any substantial change to the warnings at the time in which it was sold. The Farxiga ingested by Mr. Bustamante was in the same condition as when it was manufactured, compounded, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

86. Defendants' inadequate warnings rendered Farxiga unreasonably dangerous and defective. More specifically, Farxiga was unsafe, unreasonably dangerous and defective because Defendants:

- Failed to incorporate alternative and safer warnings;
- Failed to include adequate warnings about Farxiga's risks, the nature of the defect and/or hazards associated with its use;
- Failed to incorporate alternative, safer labeling, packaging and/or warnings to minimize the risk of harm;
- Failed to properly and adequately warn of risks such as necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failed to employ appropriate marketing, labeling, packaging, distributing, preparation for use, selling and prescribing that would have prevented or significantly reduced the risk of harm;
- Failed to employ appropriate marketing, labeling, packaging, distributing, preparation for use, selling and prescribing that would have made Farxiga safe for its intended and foreseeable uses;
- Failed to disclose that safer alternatives existed that were more effective or equally effective to treat Plaintiff's condition;
- Disregarded the health, safety and well-being of consumers of Farxiga, including Plaintiff, by failing to fully and adequately warn of dangers and defects which involved a substantial likelihood of harm, including the risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failed to provide adequate warnings addressing all known or reasonably foreseeable risks of harm;
- Failed to warn of the risks of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failed to ensure that the warnings and precautions to the medical community, physicians, Plaintiff's prescribing physician, and Plaintiff were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;
- Failed to provide the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff with adequate, clinically relevant information, safety data, and warnings concerning the adverse health risks associated with Farxiga;

- Failed to conduct adequate post-marketing safety surveillance concerning Farxiga and report that information to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;
- Failed to adequately investigate safety signals that arose from post- marketing data and report that information to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;
- Failed to continually monitor, test, and analyze data concerning safety, efficacy, and the prescribing practices for Farxiga;
- Failed to review all adverse event information and to report any information bearing on the adequacy and/or accuracy of the warnings and precautions in the Farxiga label;
- Failed to ensure that the Farxiga labeling was based on data from the human experience;
- Failed to ensure that the Farxiga labeling was informative and accurate;
- Failed to ensure that the Farxiga labeling was neither false nor misleading in any particular;
- Failed to update the Farxiga labeling based on new safety information that caused the previous labeling to become inaccurate, false, and/or misleading;
- Failed to ensure that the Farxiga labeling contained a summary of the essential scientific information needed for the safe and effective use of the drug;
- Failed to update the Farxiga labeling based on reasonable evidence of a causal association between the drug and necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failed to update the Farxiga labeling to advise the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff that taking Farxiga as prescribed may cause serious and permanent injuries such as necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);
- Failed to proactively inform the medical community that Farxiga can cause necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) through sending a "Dear Doctor" letter;
- Failed to report information concerning the efficacy, safety, and risks and/or prevalence of side effects caused by and/or associated with Farxiga to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;
- Failed to perform adequate and necessary post-marketing safety studies to determine and to analyze the risks associated with the use of Farxiga and to determine and adequately communicate the safety profile and side effects of Farxiga to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

- Failed to provide adequate post-marketing warnings and precautions after Defendants knew or should have known of the significant risks of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) in patients who have taken Farxiga;

- Failed to periodically review all medical literature concerning Farxiga and failed to report data concerning Farxiga's labeling, efficacy, or safety to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

- Failed to disclose to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff the results of testing and other information regarding the possibility that Farxiga may cause or is associated with, necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

- Failed to act as a reasonably prudent drug company in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, testing, and selling Farxiga;

- Failed to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, testing, and selling Farxiga;

- Designed, marketed, promoted and sold a product, Farxiga, for which the risks of the product outweighed its benefits;

- Failed to adequately convey the nature, severity and duration of the risk of adverse events such as necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

- Promoted and marketed Farxiga as safe and effective for the treatment of diabetes, despite the fact that Defendant knew or should have known that Farxiga was and is unsafe for this indication and that Farxiga is associated with several adverse events including an increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

- Promoted and marketed Farxiga as safe and effective for use with patients suffering from diabetes, when, in fact, it was not and is not;

- Continued to promote the safety and the efficacy of Farxiga while downplaying its risks, even after Defendant knew or should have known of the risks posed by Farxiga.

87. Defendants, individually and through their agents, employees, and/or servants, are responsible for the losses sustained by Plaintiff pursuant to Restatement Second and/or Third of Torts Section 402A, as all the elements as set forth therein have been established.

88. As a direct and proximate result of the defective nature of the drug and Defendants' lack of sufficient warnings, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against Defendants jointly, severally and individually, for all special and general damages, including pain and suffering, the costs of this action, plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT SIX

STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN

89. Plaintiff re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

90. Defendants designed, developed, researched, tested, licensed, manufactured, labeled, promoted, marketed, sold and distributed Farxiga in a defective and unreasonably dangerous condition, including the Farxiga used by Plaintiff Michael Bustamante.

91. The Farxiga ingested by Plaintiff was defectively designed due to Defendants' failures to:

- Develop and provide product label and marketing materials that accurately describe the risks of the product and do not overstate the product's benefits;
- Provide full, complete and accurate information to the FDA about Farxiga;
- Adequately test, study and develop Farxiga;
- Ensure that the benefits of Farxiga outweigh the risks;
- Conduct adequate post-market surveillance; and
- Use a safer alternative formulation.

92. The design defect rendered Farxiga more dangerous than an ordinary consumer would expect and more dangerous than other drugs available and used to treat diabetes.

93. The dangers of Farxiga were unknowable to Plaintiff and would have been considered unacceptable to the average consumer.

94. The design defect was such that the risks of Farxiga outweighed the product's utility.

95. There were practical and technically feasible alternatives that would not have reduced the utility of Farxiga and would not have cost substantially more to develop, including, but not limited to, providing a better warning with Farxiga, using an alternative diabetes treatment or developing a SGLT2 inhibitor with a different safety profile.

96. The label is part of the design of Farxiga, and therefore the design can be changed. Specifically, the label could have included a warning regarding the increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene).

97. Defendants' defective design of Farxiga was reckless, willful, wanton, fraudulent, malicious and done with reckless disregard for the health and safety of consumers such as Plaintiff.

98. Farxiga was expected to and did reach consumers such as Plaintiff without substantial change in the condition in which it was sold and without substantial change to the warnings

at the time in which it was sold. The Farxiga ingested by Plaintiff, Michael Bustamante, was in the same condition as when it was manufactured, compounded, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

99. Defendants as the designers, manufacturers, and/or promoters of pharmaceutical drugs, are held to the level of knowledge of an expert in the field. Defendants knew or should have known of the design defects in Farxiga.

100. Plaintiff and Plaintiff' physicians did not have the same knowledge or expertise as Defendants and could not have discovered the defects in Farxiga through the exercise of reasonable care.

101. Defendants, individually and through their agents, employees, and/or servants, or responsible for the losses sustained by Plaintiff and Plaintiff pursuant to Restatement Second and/or Third of Torts Section 402A, as all the elements as set forth therein have been established.

102. As a direct and proximate result of the defective nature of the drug and Defendants' lack of sufficient warnings, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against Defendants jointly, severally and individually, for all special and general damages, including pain and suffering, the costs of this action plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

COUNT SEVEN PUNITIVE DAMAGES

103. Plaintiff re-allege each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

104. The actions and inactions of the Defendants, whether taken singularly or in combination with others, were of such a character as to constitute a pattern or practice of outrageous and/or willful misconduct, fraud, wantonness, gross negligence and/or that entire want of care which reflects reckless indifference to the rights of others. As a direct and proximate result of these actions, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

105. Given the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk.

106. Defendants were actually, subjectively aware of Farxiga's defective and unreasonably dangerous nature and of the serious risks posed to persons such as Plaintiff who ingested Farxiga. Nevertheless, Defendants consciously and/or deliberately misrepresented and concealed the risks associated with Farxiga. Defendants continued to conceal and/or failed to disclose to the public, including Plaintiff and his healthcare providers, the serious complications associated with the use of Farxiga to ensure continued and increased sales of Farxiga.

107. By acting to maximize sales and profits at the expense of the health and safety of consumers such as Plaintiff, Defendants proceeded with conscious indifference to the rights, safety, and welfare of Plaintiff by failing to act to disclose these risks to regulatory agencies, the medical community, consumers of Farxiga, Plaintiff and Plaintiff' healthcare professionals. Moreover, Defendants made material misrepresentations that were false, with actual knowledge of and/or reckless disregard for their falsity, and with the intent that the representations be acted on by Plaintiff and his healthcare providers.

108. The acts and omissions of Defendants, whether taken singularly or in combination with others, constitutes outrageous and willful misconduct, fraud, wantonness, oppression, gross negligence and/or that entire want of care which reflects reckless indifference to the rights of others. As a direct and proximate result of these actions, Plaintiff suffered serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff demand judgment against Defendants jointly, severally and individually, for all special and general damages, including pain and suffering, punitive damages, the costs of this action plus pre-judgment and post-judgment interest and other such relief as the Court finds just.

REQUESTED RELIEF

109. As a direct and proximate result of the aforementioned actions and/or inactions of Defendants, Plaintiff sustained grievous injuries, suffered extreme conscious pain, suffering and discomfort, sustained a substantial loss of earnings and a loss of earning capacity and incurred substantial medical expenses;

110. Plaintiff prays that judgment to be entered against Defendants on all causes of action of this Complaint, all injuries and losses sustained, including but not limited to:

- Physical injuries including, but not limited to, destruction of critical tissue and bodily structures; necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene); invasive procedures; surgical procedures; extensive hospitalization; physical impairment, and physical incapacity;
- Past and future pain and suffering;
- Past and future mental anguish;
- Past and future humiliation;
- Past and future embarrassment;
- Past and future loss of life's pleasures and enjoyment of life;
- Past and future medical expenses that are reasonable and necessary;
- Disfigurement;
- Past loss of earnings;
- Future loss of earnings and earning capacity;
- Loss of consortium;
- Punitive damages; and
- Other injuries, the full extent of which are not yet realized.

WHEREFORE, Plaintiff demand judgment against Defendants jointly, severally and individually, for all special and general damages, including pain and suffering, punitive damages, the costs of this action, plus pre-judgment and post-judgment interest and other such relief as the Court finds just.