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Case No. N20C-06-246 FAR

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

TONY FORSYTHE AND AMANDA FORSYTHE,	)	
Plaintiffs,	)	**Case No.: _____**
ASTRAZENECA AB and ASTRAZENECA PHARMACEUCTICALS, LP	)	
Defendants.	)	**TRIAL BY JURY DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiffs, Toney and Amanda Forsythe, hereby file this Original Complaint and Demand for Jury Trial against Defendant AstraZeneca Pharmaceuticals LP ("Defendant" or "AstraZeneca"), and allege as follow:

I. Introduction

1. This an action for damages suffered by Plaintiffs caused by Defendants' negligent and wrongful conduct in connection with the development, testing, packaging, promoting, marketing, distribution, labeling and/or sale of Xigduo XR (dapagliflozin plus metformin) (hereinafter referred to "Xigduo"). Defendant sold the drug Xigduo to Plaintiff, Toney Forsythe, without warning that the drug is associated with and can cause necrotizing fasciitis of the perineum, also known as Fournier's gangrene (a life-threatening infection of the genitals and/or area around the genitals).

II. The Parties

2. At all relevant times, Plaintiffs, Toney and Amanda Forsythe, were residents of the state of Texas. Plaintiff, Toney Forsythe, was prescribed and used Xigduo, and both Plaintiffs were damaged thereby.

3. 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 Xigduo XR. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca AB manufactures, markets, distributes and sells Xigduo XR throughout the United States.

4. Defendant AstraZeneca Pharmaceuticals LP is a Delaware Limited Partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850-5437. AstraZeneca Pharmaceuticals LP, which does business as AstraZeneca US is a subsidiary of AstraZeneca AB. AstraZeneca Pharmaceuticals LP is the distributor of Xigduo XR. Accordingly, Defendant AstraZeneca Pharmaceuticals LP may be served with process through serving its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

5. At all times relevant to this Complaint, AstraZeneca AB and AstraZeneca Pharmaceuticals LP were each, individually and in concert with 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, Xigduo XR.

III. Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action and the parties.

7. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, is a citizen of Delaware based on the citizenship of its general and

limited partners and maintains its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19801.

8. Substantial activities relating to the design, development, marketing, promotion and sales of Xigduo XR were performed by Defendants in Delaware. Defendants made decisions regarding the design, testing, regulatory communications and processes, marketing strategy, labeling and warnings content for Xigduo XR in the State of Delaware.

9. Defendants regularly solicited or transacted business in Delaware. Defendants were engaged, either directly or indirectly, in the business of designing, developing, marketing, promoting, distributing, and selling prescription drugs products, including Xigduo XR within Delaware, with a reasonable expectation that the products would be used or consumed in Delaware.

10. Defendants disseminated inaccurate, false, and misleading information about Xigduo XR to health care professionals in Delaware, with a reasonable expectation that such information would be used and relied upon by health care professionals in Delaware.

11. At all times relevant to this action, Defendants consented to the jurisdiction of this Court.

12. There is no federal jurisdiction over this matter because Plaintiff asserts claims against a forum defendant. Defendant AstraZeneca Pharmaceuticals LP is a citizen of Delaware. 28 U.S.C. § 1441(b)(2) ("A civil action…may not be removed if any of the parties properly joined and served as defendants is a citizen of the State in which such action is brought.").

13. This lawsuit is not subject to removal based on the existence of a federal question. Plaintiff asserts common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws or treatises of the United States. 28 U.S.C. § 1447(c).

14. Venue in this action properly lies in Delaware because Defendant AstraZeneca Pharmaceuticals LP is a Delaware entity.

IV. Factual Background

15. Xigduo is an oral Type 2 diabetes medication. It is part of the gliflozin drug class that is referred to generally as sodium-glucose transporter 2 (SGLT2) inhibitors. SGLT2 is a protein in humans that facilitates glucose reabsorption in the kidney with the goal of lowering blood glucose. SGLT2 inhibitors reduce blood sugar levels by reducing glucose reabsorption through the user's kidneys and increasing glucose excretion in the user's urine.

16. 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.

17. On October 29, 2014, the United States Federal Administration ("FDA") approved Xigduo, a combination drug therapy comprised of Xigduo (dapagliflozin propanediol), a SGLT2[1] inhibitor, combined with metformin hydrochloride, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Since that time, AstraZeneca has

[1] Sodium glucose cotransporter 2

held the NDA for Xigduo and has assumed all rights, responsibilities and potential liabilities associated with or concerning Xigduo.

Xigduo's Association with Necrotizing Fasciitis of the Genital/Perianal/Gluteal Regions (Including Fournier's Gangrene)

18. SLGT2 inhibitors, including Xigduo, are indicated for glycemic control in Type 2 adult diabetics. Nevertheless, in order to increase market share, Defendants marketed and continue to market Xigduo to both healthcare professionals and direct to consumers for off-label purposes, including but not limited to weight loss and reduced blood pressure.

19. 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.

20. Since Xigduo'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.

21. With regard to Fournier's gangrene, a form of necrotizing fasciitis of the genital/perianal/gluteal regions, the FDA has observed that an increased incident 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 a SGLT2 inhibitor such as Xigduo XR. 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.

22. 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:

a. Xigduo's selectivity for the SGLT1 receptor;

b. Animal studies demonstrating an increased risk of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene when given Xigduo XR);

c. 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 Xigduo XR;

d. 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 Xigduo XR;

e. Adverse event report analysis demonstrating an increased risk of reports for necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) for people taking Xigduo XR;

f. 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 Xigduo XR.

g. The basics of infectious disease science.

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

Defendants' Failures to Properly Design Xigduo and Warn about Xigduo's Risk

24. Despite their knowledge of data including that Xigduo is associated with and/or casually related to necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene), Defendants: (a) promoted and marketed Xigduo 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 Xigduo; (d) continued to defend Xigduo against claims that it caused necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene); (e) minimized unfavorable findings; (f) did not conduct the necessary additional studies to properly evaluate this risk prior to marketing the drug to the general public and (g) recommended, promoted and advertised Xigduo for weight loss, an indication not approved by the FDA.

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

26. Defendants published advertisements on their company websites and issued press releases announcing information about Xigduo. 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 Xigduo. (Ex. 1).

27. To the best of Plaintiff's 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 Xigduo 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 Xigduo.

28. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Xigduo, both as to its ability to lower glucose, and its ability to promote weight loss for patients taking the drug. Defendants misrepresented that Xigduo 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).

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

30. Consumers of Xigduo and their prescribing physicians relied on Defendants' false representations, recommendations, promotions and advertisements 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.

31. Although Defendants had a duty to warn Plaintiff's prescribing physicians about the risks of Xigduo 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 Xigduo.

32. At all times herein mentioned, the officers and directors of Defendants' participated in, authorized, and directed the production and promotion of Xigduo 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

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

34. Yet, as a direct result of Defendants' conduct, Plaintiff Toney Forsythe was prescribed Xigduo by his treating physician and began taking Xigduo in April 2015 to treat his diabetes but also to promote weight loss. Plaintiff ingested and used Xigduo as prescribed by his doctor and in a foreseeable manner until about September 2017. The Xigduo 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.

35. Plaintiff agreed to initiate treatment with Xigduo in an effort to treat Plaintiff's Type 2 diabetes and to aid in weight loss. In doing so, Plaintiff relied on claims made by

Defendants that Xigduo was safe and effective for the treatment of diabetes. Plaintiff also relied upon Defendants' recommendations, promotion and advertisements that Xigduo was safe and effective in inducing weight loss. Had Plaintiff and Plaintiff's physician(s) known the true risks associated with the use of SGLT2 inhibitors, including Xigduo, Plaintiff would not have been prescribed Xigduo, and Plaintiff would have refused to take Xigduo. Additionally, and alternatively, at a minimum, Plaintiff would have been adequately monitored for side effects from Xigduo, and as a result, would not have suffered injuries and damages from using Xigduo.

36. Plaintiff's prescribing and treating physician(s) relied on representations made by Defendants that Xigduo has been clinically shown to improve glycemic control and was generally safe and effective. Plaintiff's prescribing physicians further relied upon Defendants' recommendation, promotion and advertisement of Xigduo for weight loss. 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.

37. After beginning treatment with Xigduo, 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 genital/perianal/gluteal regions and other injuries, the full extent of which are not yet realized. These debilitating injuries required invasive procedures, surgical procedures and extensive hospitalization.

38. Plaintiff was initially diagnosed with Fournier's gangrene in September 2015 and he underwent emergency surgery, with follow up irrigation and debridement procedures performed while being hospitalized for an extended period of time.

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 test Xigduo, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, promotion of Xigduo for weight loss, willful and wanton failure to provide adequate instructions and warnings, and willful misrepresentations concerning the nature and safety of Xigduo. 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 Xigduo 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 SGLT2 inhibitors like Xigduo.

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 Xigduo 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 a SGLT2 inhibitor such as Xigduo. 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, Xigduo'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 Xigduo 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 Xigduo. There was no way, at the time Plaintiff was diagnosed, that Plaintiff, exercising ordinary diligence, could have discovered that Plaintiff's injuries might be related to the Xigduo that Plaintiff had ingested. Thus, under the applicable discovery rule, Plaintiff's 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's causes of action. Defendants' fraudulent concealment resulted in such delay.

47. Defendants are, and were, under a continuing duty to disclose that Xigduo 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 Xigduo 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 Xigduo.

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 Xigduo.

CAUSES OF ACTION

COUNT ONE
NEGLIGENCE

52. Plaintiff repeats and re-alleges 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 Xigduo.

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 Xigduo. 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 Xigduo. 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 Xigduo, Defendants knew or reasonably should have known that Xigduo 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:

a. Failing to properly and thoroughly test Xigduo before releasing the drug to market;

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

c. Failing to conduct sufficient post-market testing and surveillance of Xigduo;

d. Designing, compounding, manufacturing, advertising, distributing and selling Xigduo 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 disclose to health care professionals the causal relationship and/or association of Xigduo to adverse health conditions including necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

f. 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 Xigduo and the comparative severity of such adverse effects;

g. 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);

h. Failing to fully and accurately disclose the clinical safety and effectiveness profile of Xigduo;

i. Failing to exercise due care when advertising and promoting Xigduo; and

j. Negligently continuing to manufacture, market, advertise and distribute Xigduo 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 Xigduo was and is unreasonably defective in design as follows:

a. Xigduo unreasonably increased the risks of developing Plaintiff's injuries as complained of herein;

b. Xigduo was not reasonably safe for its intended use;

c. Xigduo is more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with products that treat Plaintiff's condition;

d. Xigduo was not adequately tested;

e. Xigduo's risks exceeded the benefit of the drug; and

f. Xigduo 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 Xigduo.

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, testing, marketing, labeling, distribution and sale of Xigduo.

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

59. Xigduo was expected to, and did, reach consumers such as Plaintiff without any substantial change in the condition in which it was sold and without any substantial change to the warnings at the time in which it was sold. The Xigduo ingested by Plaintiff was in the same condition as when it was manufactured, compounded, inspected, marketed, labeled, promoted, distributed and sold by Defendants. Plaintiff used Xigduo for its intended purpose and in a manner normally intended.

60. The harm caused by Xigduo far outweighed the benefits, rendering Xigduo 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 Xigduo to make it less dangerous. When Defendants manufactured Xigduo, the state of the industry's scientific knowledge was such that a less risky design was attainable.

61. At the time Xigduo 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 Xigduo. 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 demands 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-alleges 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 Xigduo.

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

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

a. Defendants are merchants with respect to Xigduo;

b. Defendants sold Xigduo in a defective, unsafe and inherently dangerous condition;

c. Xigduo 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.

d. Xigduo 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

e. Plaintiff is a natural person who would have been reasonably expected to use, consume or be affected by Xigduo 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 Xigduo was safe and fit for its intended use.

68. By selling Plaintiff and Plaintiff's 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 demands 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-alleges 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:

a. Defendants had reason to know of the particular purpose for which Xigduo was intended;

b. Defendants had reason to know that healthcare professionals and consumers buying Xigduo relied upon Defendants' skill and expertise in designing, manufacturing, labeling and selling a safe and effective pharmaceutical product when prescribing and ingesting Xigduo for the treatment of diabetes.

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

d. Plaintiff was relying on Defendants' skill or judgment to furnish a suitable product.

72. Plaintiff and Plaintiff's 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 Xigduo, 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 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 demands 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-alleges 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 Xigduo was safe for its intended use, effective as a treatment for diabetes, and as otherwise described in this Complaint. Xigduo did not conform to these express representations, including, but not limited to, the representation that

Xigduo was safe and effective and the representation that Xigduo 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 Plaintiff's use of Xigduo and Plaintiff and Plaintiff's health care providers relied on Defendants' warranties in deciding to prescribe and use Xigduo.

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

78. Xigduo did not, and does not, conform to Defendants' express representations and description of the goods because Xigduo 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 Xigduo and by describing Xigduo as safe and effective such that Plaintiff and her healthcare providers relied upon such affirmations and descriptions as a part of the basis of the bargain, an express warranty was created that Xigduo 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 express 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 demands 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 repeats and re-alleges 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 Xigduo in an unreasonably dangerous condition, including the Xigduo used by Plaintiff.

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 Xigduo was manufactured, labeled, distributed, sold and ingested by Plaintiff, 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 Xigduo. 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. Xigduo was expected to and did reach consumers such as Plaintiff without any substantial change in the condition in which it was sold and without any substantial change to the warnings at the time in which it was sold. The Xigduo ingested by Plaintiff 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 Xigduo unreasonably dangerous and defective. More specifically, Xigduo was unsafe, unreasonably dangerous and defective because Defendants:

a. Failed to incorporate alternative and safer warnings;

b. Failed to include adequate warnings about Xigduo's risks, the nature of the defect and/or hazards associated with its use;

c. Failed to incorporate alternative, safer labeling, packaging and/or warnings to minimize the risk of harm;

d. Failed to properly and adequately warn of risks such as necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

e. 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;

f. Failed to employ appropriate marketing, labeling, packaging, distributing, preparation for use, selling and prescribing that would have made Xigduo safe for its intended and foreseeable uses;

g. Failed to disclose that safer alternatives existed that were more effective or equally effective to treat Plaintiff's condition;

h. Disregarded the health, safety and well-being of consumers of Xigduo, 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);

i. Failed to provide adequate warnings addressing all known or reasonably foreseeable risks of harm;

j. Failed to warn of the risks of necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene).

k. 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;

l. 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 Xigduo.

m. Failed to conduct adequate post-marketing safety surveillance concerning Xigduo and report that information to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

n. 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;

o. Failed to continually monitor, test, and analyze data concerning safety, efficacy, and the prescribing practices for Xigduo;

p. 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 Xigduo label;

q. Failed to ensure that the Xigduo labeling was based on data from the human experience;

r. Failed to ensure that the Xigduo labeling was informative and accurate;

s. Failed to ensure that the Xigduo labeling was neither false nor misleading;

t. Failed to update the Xigduo labeling based on new safety information that caused the previous labeling to become inaccurate, false, and/or misleading;

u. Failed to ensure that the Xigduo labeling contained a summary of the essential scientific information needed for the safe and effective use of the drug;

v. Failed to update the Xigduo 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);

w. Failed to update the Xigduo labeling to advise the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff that taking Xigduo as prescribed may cause serious and permanent injuries such as necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

x. Failed to proactively inform the medical community that Xigduo can cause necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene) through sending a "Dear Doctor" letter;

y. Failed to report information concerning the efficacy, safety, risks and/or prevalence of side effects caused by and/or associated with Xigduo to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

z. Failed to perform adequate and necessary post-marketing safety studies to determine and to analyze the risks associated with the use of Xigduo and to determine and adequately communicate the safety profile and side effects of Xigduo to the medical community, physicians, Plaintiff's prescribing physicians, and Plaintiff;

aa. 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 Xigduo;

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

cc. 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 Xigduo may cause or is associated with, necrotizing fasciitis of the genital/perianal/gluteal regions (including Fournier's gangrene);

dd. 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 Xigduo;

ee. 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 Xigduo;

ff. Designed, marketed, promoted and sold a product, Xigduo, for which the risks of the product outweighed its benefits;

gg. 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;

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

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

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

kk. Recommended, promoted and advertised Xigduo as safe and effective for weight loss when Xigduo was not approved by the FDA for weight loss.

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, Defendants' lack of sufficient warnings and Defendants' off-label recommendation, promotion and advertisement of Xigduo for weight loss, 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 demands 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-alleges 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 Xigduo in a defective and unreasonably dangerous condition, including the Xigduo used by Plaintiff.

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

a. Develop and provide product label and marketing materials that accurately describe the risks of the product and do not overstate the product's benefits;

b. Provide full, complete and accurate information to the FDA about Xigduo;

c. Adequately test, study and develop Xigduo;

d. Ensure that the benefits of Xigduo outweigh the risks;

e. Conduct adequate post-market surveillance;

f. Use a safer alternative formulation;

g. Recommend, promote and advertise Xigduo solely for its FDA-approved indication of treating Type 2 diabetes.

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

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

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

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

96. The label is part of the design of Xigduo, 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 Xigduo was reckless, willful, wanton, fraudulent, malicious and done with reckless disregard for the health and safety of consumers such as Plaintiff.

98. Xigduo 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 Xigduo ingested by Plaintiff 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 Xigduo.

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

101. 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.

102. As a direct and proximate result of the defective nature of the drug, Defendants' lack of sufficient warnings and Defendants' off-label recommendation, promotion and advertisement of Xigduo for weight loss, 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 demands 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-alleges 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 Xigduo's defective and unreasonably dangerous nature and of the serious risks posed to persons such as Plaintiff who ingested Xigduo. Nevertheless, Defendants consciously and/or deliberately misrepresented and concealed the risks associated with Xigduo. Defendants continued to conceal and/or failed to disclose to the public, including Plaintiff and her healthcare providers, the serious complications associated with the use of Xigduo to ensure continued and increased sales of Xigduo.

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 Xigduo, Plaintiff and Plaintiff's 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 demands 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.

COUNT EIGHT
LOSS OF CONSORTIUM AS TO PLAINTIFF AMANDA FORSYTHE

109. Plaintiffs 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.

110. At all times material to this lawsuit, Plaintiff Amanda Forsythe has been married to Plaintiff Toney Forsythe and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

111. Plaintiffs Toney Forsythe and Amanda Forsythe allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered, as a result of the injuries and damages to Plaintiff Toney Forsythe caused by Xigduo, Plaintiff Amanda Forsythe has suffered great emotional pain and mental anguish.

112. As a direct and proximate result of the foregoing, Plaintiff Amanda Forsythe was deprived of the comfort and enjoyment of the services and society of her spouse, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Amanda Forsythe's injuries and damages will continue into the future. Accordingly, the Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands 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

113. 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;

114. Plaintiffs pray 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:

a. 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.

b. Past and future pain and suffering;

c. Past and future mental anguish;

d. Past and future humiliation;

e. Past and future embarrassment;

f. Past and future loss of life's pleasures and enjoyment of life;

g. Past and future medical expenses that are reasonable and necessary;

h. Disfigurement;

i. Past loss of earnings;

j. Future loss of earnings and earning capacity;

k. Punitive damages; and

l. Other injuries, the full extent of which are not yet realized.

WHEREFORE, Plaintiffs 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.

JURY TRIAL

Plaintiff respectfully request a trial by jury in the above case as to all issues.

Respectfully submitted this, the 23rd day of June 2020:

s/ Raeann Warner
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