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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ALABAMA

ANGELA HARDY, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY; ASTRAZENECA PHARMACEUTICALS, LP; MCKESSON CORPORATION, Defendants	Case No.: **COMPLAINT FOR DAMAGES** JURY TRIAL DEMANDED

COMES NOW Plaintiff and alleges against Defendants Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation as follows:

I. INTRODUCTION

1. This is an action for damages relating to the Defendants' design, manufacture, sale, marketing, advertising, promotion, labeling, packaging, and distribution of their drug Saxagliptin. Defendants sell their Saxagliptin drug under the brand names Onglyza and Kombiglyze XR. Saxagliptin, in any of its forms or products, including Onglyza and Kombiglyze XR, shall herein be referred to as "Saxagliptin."

2. Saxagliptin is prescribed to help lower blood sugar levels in persons with type 2 diabetes mellitus.

3. The use of Saxagliptin can cause heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions.

4. Plaintiff ingested Saxagliptin, and as a result of use of the drug suffered injuries.

II. GENERAL ALLEGATIONS

5. Plaintiff, Angela Hardy ("Plaintiff"), by and through Plaintiff's attorneys, Sanders Phillips Grossman, LLC, brings this action for personal injuries suffered as a result of being prescribed and ingesting the defective and unreasonably dangerous prescription drug(s) Onglyza and/or Kombiglyze XR.

6. Onglyza and Kombiglyze XR are prescribed to help lower blood sugar levels in persons with type 2 diabetes mellitus, and at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants Bristol-Meyers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation (collectively "Defendants"). On information and belief, Plaintiff ingested Saxagliptin resulting in injuries.

III. PARTIES

7. At all times relevant to this action, Plaintiff, was an individual, citizen and resident of the state of Alabama.

8. Plaintiff ingested Saxagliptin from approximately 2014 to 2016, resulting in injuries.

9. Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation with its principal place of business at 345 Park Ave., New York, NY 10154. At all relevant times, BMS has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling and marketing of Saxagliptin within the state of Alabama.

10. Defendant AstraZeneca Pharmaceuticals, LP ("AZ") is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, DE 19850. At all relevant times, AZ has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling and marketing of Saxagliptin within the state of Alabama.

11. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business at One Post Street, San Francisco, CA 94104. At all relevant times, McKesson has conducted business and derived substantial revenue from its

manufacturing, advertising, distributing, selling and marketing of Saxagliptin within the state of Alabama.

12. Hereinafter the aforementioned Defendants may collectively be referred to as "Defendants."

13. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

14. At all relevant times, Defendants acted in concert with one another to fraudulently convey false and misleading information concerning the safety and efficacy of Saxagliptin and to conceal the risks of serious adverse events, including heart failure, congestive heart failure, cardiac failure, death from heart failure and other adverse effects associated with Saxagliptin from the public, Plaintiff, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to those treated with Saxagliptin, including Plaintiff. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiff would not have ingested Saxagliptin.

15. At all times alleged herein, Defendants 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, and/or advertising for sale or selling Saxagliptin.

16. At all times alleged herein, Defendants were authorized to conduct or engage in business within the state of Alabama and supplied Saxagliptin within the state of Alabama. Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing Saxagliptin within the state of Alabama.

17. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

18. The amount in controversy exceeds the jurisdictional limits of this court.

IV. JURISDICTION AND VENUE

19. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 as complete diversity of citizenship exists between Plaintiff and Defendants and the matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

20. This Court has jurisdiction over the non-resident Defendants because they have conducted business in the state of Alabama. Defendants have committed a tort in whole or in part in the state of Alabama and have regular and continuing contacts with Alabama.

21. In addition, venue of this case is proper in the state of Alabama pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the state of Alabama.

V. FACTUAL ALLEGATIONS

22. Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels and/or hyperglycemia. Type 2 diabetics have an increased risk of cardiovascular disease, which is the leading cause of morbidity and mortality in the patient population. Therefore, it is critical that drugs developed to allegedly help prevent type 2 diabetes do not increase the risk of cardiovascular adverse events in users. With full knowledge of the susceptibility of type 2 diabetics to cardiovascular related adverse events, Defendants developed their drugs Onglyza and Kombiglyze XR to market and sell them to type 2 diabetics to allegedly lower adverse complications associated with type 2 diabetes.

23. Saxagliptin works by inhibiting the proteolytic activity of DPP4, thereby potentiating the action of Glucagon-like peptide-1 (GLP-1), an anti-hyperglycemic hormone, known as an incretin. This induces glucose-dependent stimulation of insulin secretion while suppressing glucagon secretion, which may help Saxagliptin users lower their HA1c.

24. DPP4 inhibitors, including Saxagliptin, inhibit natural enzymes from cleaving, or stopping, the endogenous GLP-1, which enables the stimulation of insulin to continue longer than what naturally occurs after meals in the postprandial state. Endogenous GLP-1's half-life is

approximately two minutes without Saxagliptin exposure, but survives for at least three hours during Saxagliptin exposure. Therefore, Saxagliptin manipulates the natural biological incretin effect by enabling the process to continue for an exponentially greater period of time than what the human body has adapted as a sufficient and safe period of time. At no time during the development of its Saxagliptin drugs did Defendants perform adequate studies to determine if their drug, and its drastic alterations of the natural incretin hormone cycle, may cause increased risks of cardiovascular related adverse events. Such studies are essential when developing, and then marketing, diabetic drugs to individuals already at an increased cardiovascular risk.

25. In December 2008, with knowledge of the increased cardiovascular risk type 2 diabetics suffer from, the FDA issued important guidance regarding this topic to companies developing anti-diabetic drugs, including Defendants. The FDA's memorandum, entitled Final Guidance for Industry, *Diabetes Mellitus: Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes,* stated applicants of new anti-diabetic medications for the treatment of type 2 diabetes should demonstrate their products are not associated with an unacceptable increase in cardiovascular risk.[1] Despite this guidance being issued during the development of Defendants' drugs, Defendants failed to perform adequate clinical trials to determine if their drugs created such an increased risk. Instead of adequately assessing the potential, and now established, significant risk of heart failure, congestive heart failure, cardiac failure, and death related to those events, prior to marketing and selling Saxagliptin nationwide to millions of type 2 diabetics, Defendants ignored patient safety and sold Saxagliptin before studying the risks. Defendants marketed and sold Saxagliptin for nearly five years before completing an adequately powered and designed study of the risks of heart failure, congestive heart failure, cardiac failure, and death related to those events.

26. On July 31, 2009, Defendants began marketing Onglyza. On November 5, 2010, Defendants began marketing Kombiglyze XR. Defendants marketed both drugs as treatments for type 2 diabetes and agents to help reduce adverse complications associated with the disease.

[1] *Id.*

At no time did Defendants perform adequate studies or adequately warn that Onglyza and Kombiglyze XR increased the risk of cardiovascular related adverse events.

27. After Defendants began selling and making substantial profits off their drugs, Onglyza and Kombiglyze XR, Defendants finally conducted what the FDA guidance recommended back in December 2008– a Cardiovascular Outcome Trial ("CVOT") for Saxagliptin.

28. The CVOT for Saxagliptin entitled, "Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus — Thrombolysis in Myocardial Infarction 53" (SAVOR-TIMI 53 or more simply, "SAVOR"), found Saxagliptin users had a statistically significant increased risk of being hospitalized due to heart failure.

29. After receiving and reviewing the disturbing findings from the SAVOR trial, the FDA requested the raw clinical trial data, free from manipulation by Defendants, and performed its own analysis of the SAVOR data. Following the FDA's detailed analysis and review of the SAVOR safety signal for hospitalization for heart failure, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee convened and voted 14 to 1 for the FDA to order Defendants to add a heart failure warning to its Saxagliptin drugs. The single member who voted against adding the warning stated a warning was insufficient and the drug should instead be withdrawn from the US market.[2] Despite the SAVOR findings and despite the FDA Advisory Committee voting to add a warning (or remove the drugs from the market), Defendants failed and continue to fail to warn. Once again, Defendants place sales over patient safety.

30. In addition to Defendants refusing and failing to warn of the risks of heart failure, congestive heart failure, cardiac failure and death, Defendants' Saxagliptin drugs lack any benefit sufficient to tolerate the risks posed by its use because other anti-diabetes drugs are available that do not carry the increased cardiac risks of Saxagliptin.

[2] Diabetes in Control (April 17, 2015) "FDA Panel Recommends New CV Safety Warnings on Onglyza and Nesina DPP-4s," available from: http://www.diabetesincontrol.com/articles/diabetes-news/17836-fda-panel-recommends-new-cv-safety-warnings-on-onglyza-and-nesina-dpp-4s-

31. Defendants, with knowledge of the true relationship between use of Saxagliptin and heart failure, congestive heart failure, cardiac failure, and death related to those events, promoted and continue to promote Saxagliptin as a safe and effective treatment for type 2 diabetes mellitus.

32. Defendants over-promoted Saxagliptin and under-warned about Saxagliptin's risks through various avenues including, but not limited to, the following:

a. in print marketing, advertising, and promotional materials;

b. on Defendant-owned, controlled, or supported websites and blogs;

c. in materials and advertisements to Plaintiff and consumers stating the use of Saxagliptin is safe; and

d. in promoting Saxagliptin to doctors, clinics, and users as being safer than (or as safe as) other drugs for the treatment of type 2 diabetes mellitus.

33. At no time did Defendants perform adequate safety testing on Saxagliptin prior to marketing their drugs to the American public and failed to do so until performing the SAVOR trial.

34. Despite the findings of the SAVOR trial, Defendants still have not undertaken efforts to change the labels and reference materials for Saxagliptin to include a reference or warning regarding heart failure, congestive heart failure, cardiac failure, and death related to those events.

VI. PLAINTIFF'S USE OF SAXAGLIPTIN

35. On information and belief, Plaintiff was prescribed and ingested Saxagliptin at various times.

36. On information and belief, Plaintiff used Saxagliptin manufactured, packaged, marketed, sold and/or distributed by Defendants. The Saxagliptin reached Plaintiff without substantial change in the drug's condition.

37. On information and belief, while using Saxagliptin, and as a direct and proximate result thereof, Plaintiff developed serious and/or permanent adverse effects including, but not limited to, heart failure, congestive heart failure, and cardiovascular injury.

38. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

39. At all relevant times, Defendants had knowledge that there was a significant increased risk of adverse events associated with Saxagliptin including heart failure, congestive heart failure, cardiac failure, and death related to those events, and despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of Saxagliptin.

40. Despite such knowledge, Defendants knowingly, purposely, and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers, and the public of the increased risk of serious injury associated with using Saxagliptin, including, but not limited to, heart failure, congestive heart failure, cardiac failure, and death related to those events.

41. On information and belief, Plaintiff's prescribing physicians would not have prescribed Saxagliptin to Plaintiff, would have changed the way in which they treated Plaintiff's relevant conditions, changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of Saxagliptin, and discussed with Plaintiff the true risks of heart failure, congestive heart failure, cardiac failure, and death related to those events, and other serious adverse events had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Saxagliptin.

42. On information and belief, Plaintiff's prescribing health care providers were unaware of the true degree, incidence, and risk of heart failure, congestive heart failure, cardiac failure, and death related to those events associated with the use of Saxagliptin, and, if they had been informed, would have used and prescribed alternative therapies to Plaintiff.

43. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, heart failure, congestive heart failure, and a cardiovascular injury, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

44. As a direct and proximate result of Defendants' conduct, Plaintiff incurred obligations and expenses for medical care, testing and treatment. As a direct and proximate result of Defendants' conduct, Plaintiff suffered loss of income, wages, profits and commissions, diminishment of earning potential, and other pecuniary losses.

45. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

VII. DELAYED DISCOVERY

46. Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with Saxagliptin.

47. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

48. No limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between the use of Saxagliptin and the harm suffered as a result. As such, Plaintiff hereby invokes the discovery rule based on the fact that this Complaint is filed well within the statutory period after Plaintiff knew or should have known the facts alleged herein.

49. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

50. Additionally, each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

VIII. CAUSES OF ACTION

COUNT I

DESIGN DEFECT

Plaintiff incorporates by reference the factual allegations of this Complaint as though set forth in full in this cause of action and further alleges:

51. At all relevant and material times, the Defendants designed, manufactured, packaged, marketed, advertised, distributed, and sold Saxagliptin, placing the products into the stream of commerce.

52. At all relevant and material times, Saxagliptin was designed, manufactured, packaged, marketed, advertised, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

53. Saxagliptin was expected to reach, and did reach, users and consumers, including Plaintiff, without any alterations or changes in their defective and unreasonably dangerous condition.

54. Saxagliptin was used by Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

55. Saxagliptin was defective and unreasonably dangerous when each product entered the stream of commerce in one or more of the following particulars:

a. Saxagliptin contained manufacturing and design defects in that each product caused and/or increased the risk of experiencing an adverse event, including, but not limited to heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions.

b. Saxagliptin was not safe because the health risks associated with each product outweighed the benefits.

c. Saxagliptin was marketed and promoted for use when they carried an unreasonable and unnecessary risk of serious injury.

d. Saxagliptin was insufficiently and/or inadequately tested by Defendants.

e. Saxagliptin was not safe due, in part, to inadequate and defective instructions and inadequate and defective warnings provided by Defendants.

f. Saxagliptin was unreasonably dangerous in that, as designed, the risks of serious injury posed by using the products exceeded any benefits the products were designed to or might in fact bestow.

g. Saxagliptin was defective in design in that the products neither bore, nor were packaged with, nor were accompanied by, warnings adequate to alert users, including Plaintiff, of the increased risks associated with using the products, including, but not limited to, the risk of heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions

h. Saxagliptin was not accompanied by adequate warnings and instructions for use that included adequate information to fully apprise users, consumers, and the medical, pharmaceutical and scientific communities of the potential risks and serious side effects associated with using the products.

i. Saxagliptin was unsafe for normal or reasonably anticipated use. Said products were defective and unreasonably dangerous in design, construction, and/or composition.

j. Saxagliptin was defective and unreasonably dangerous, because the products did not conform to representations made by the manufacturer of the product.

k. Saxagliptin was defective and unreasonably dangerous due to inadequate warnings, inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

56. Saxagliptin, as manufactured and supplied by the Defendants, was defective due to inadequate warnings and instructions because after Defendants knew or should have known of the risk of injuries from use, Defendants failed to provide adequate warnings to the medical community and the consumers to whom the drugs were directly marketed and advertised; and, further, Defendants continued to affirmatively promote Saxagliptin as safe and effective.

57. A reasonable person who had actual knowledge of the increased risks associated with using Saxagliptin would have concluded that Saxagliptin should not have been marketed to or used by Plaintiff and Plaintiff's physicians.

58. Despite the fact Defendants knew or should have known of the defective nature of Saxagliptin, Defendants continued to design, manufacture, and sell Saxagliptin so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by Saxagliptin.

59. Plaintiff was prescribed and ingested Saxagliptin manufactured, packaged, marketed, sold and/or distributed by Defendants at various times.

60. The Saxagliptin reached Plaintiff without substantial change in the drug's condition.

61. While using Saxagliptin, and as a direct and proximate result thereof, Plaintiff developed serious and/or permanent adverse effects including, but not limited to, heart failure, congestive heart failure, and cardiovascular injury.

62. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

63. Plaintiff and the non-defendant health care providers involved could not, through the exercise of reasonable care, have discovered the risk of serious injury associated with and/or caused by Saxagliptin.

64. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by Saxagliptin.

65. Had adequate information regarding the safety of the products been provided to Plaintiff, Plaintiff would not have used Saxagliptin.

66. Plaintiff's prescribing physicians would not have prescribed Saxagliptin to Plaintiff, would have changed the way in which they treated Plaintiff's relevant conditions, changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of Saxagliptin, and discussed with Plaintiff the true risks of heart failure, congestive heart failure, cardiac failure, and death related to those events, and other serious adverse events had Defendants provided said physicians with an appropriate and adequate information regarding the risks associated with the use of Saxagliptin.

67. Plaintiff's prescribing health care providers were unaware of the true degree, incidence, and risk of heart failure, congestive heart failure, cardiac failure, and death related to those events associated with the use of Saxagliptin, and, if they had been informed, would have used and prescribed alternative therapies to Plaintiff.

68. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

69. As a direct and proximate consequence of Defendants negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff suffered the injuries and damages alleged herein.

70. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, heart failure, congestive heart failure, and a cardiovascular injury, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

71. As a direct and proximate result of Defendants' conduct, Plaintiff incurred obligations and expenses for medical care, testing and treatment. As a direct and proximate result of Defendants' conduct, Plaintiff suffered loss of income, wages, profits and commissions, diminishment of earning potential, and other pecuniary losses.

72. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT II

NEGLIGENCE

Plaintiff incorporates by reference the factual allegations of this Complaint as though set forth in full in this cause of action and further alleges:

73. Defendants negligently manufactured, designed, labeled, packaged, distributed, marketed, advertised, and sold Saxagliptin.

74. At all relevant and material times, Defendants had a duty to Plaintiff to exercise reasonable care in the design, manufacture, advertising, marketing, labeling, packaging,

distribution, post-market safety monitoring, reporting of adverse events, and sale of Saxagliptin, including a duty to ensure that the products did not cause users such as Plaintiff to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

75. Defendants breached their duty of care to Plaintiff and were negligent in their actions, misrepresentations, and omissions in numerous ways including the following:

a. Failing to perform adequate testing concerning the safety of Saxagliptin, which would have shown Saxagliptin created a high risk of unreasonable, dangerous side effects, including causing and increasing the risk of heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions and other adverse effects, which would have permitted adequate and appropriate warnings to have been given by Defendants to prescribing physicians and the consuming public, including Plaintiff;

b. Failing to design Saxagliptin so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

c. Failing to conduct adequate pre-clinical and clinical testing to determine the safety of Saxagliptin;

d. Failing to report to the FDA, the medical community, and the general public the Saxagliptin data which indicated risks associated with using the product;

e. Failing to conduct post-market monitoring and surveillance of Saxagliptin and analysis of adverse event reports;

f. Designing, manufacturing, marketing, advertising, distributing, and selling Saxagliptin to consumers, including Plaintiff, without an adequate warning of risks associated with using the products and without proper and

adequate instructions to avoid the harm which could foreseeably occur as a result of using the products;

g. Failing to exercise due care when advertising, promoting, and selling Saxagliptin;

h. Failing to use due care in the preparation, design and development of Saxagliptin to prevent, avoid, or minimize the risk of injury to individuals when the products were used;

i. Failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

j. Failing to accompany Saxagliptin with proper warnings regarding all possible risks associated with using the products;

k. Failing to use due care in the manufacture, inspection, and labeling of Saxagliptin to prevent risk of injuries to individuals who used the products;

l. Failing to provide adequate and accurate training and information to the sales representatives who sold the products;

m. Failing to educate healthcare providers and the public about the safest use of the products;

n. Failing to give healthcare providers adequate information to weigh the risks of serious injury associated with the products;

o. Failing to test and inspect Saxagliptin in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;

p. Failing to warn Plaintiff of the danger of adverse medical conditions from the use of Saxagliptin; and

q. Failing to label Saxagliptin to adequately warn Plaintiff of the serious adverse side effects with the use of Saxagliptin.

76. Defendants advertised, marketed, sold and distributed Saxagliptin despite the fact that Defendants knew or should have known of the increased risks associated with using the products, including but not limited to heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions and other adverse effects of which Plaintiff and Plaintiff's healthcare providers would not have been aware.

77. Defendants, individually and collectively, had a duty to warn the FDA, their customers, the medical community, and the public about the increased risk of injury, but failed to do so.

78. Defendants are guilty of negligence *per se* in that the Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations.

a. The Defendants' acts and omissions, including but not limited to Defendants' off-label marketing, constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons, such as Plaintiff, were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injuries.

b. The Defendants' also failed to report adverse events as required by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons, such as Plaintiff, were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injuries.

79. Despite the fact Defendants knew or should have known that Saxagliptin increased the risk of serious injury including but not limited to heart failure, congestive heart failure, cardiac failure, death from heart failure, and other serious health conditions, Defendants continued to manufacture, market, advertise, sell and distribute Saxagliptin to consumers, including Plaintiff.

80. Defendants negligently and recklessly represented to Plaintiff, physicians, and other persons and professionals Defendants knew would justifiably rely on the representations, that Saxagliptin was safe to use and that the utility of the products outweighed any risk in use for their intended purposes.

81. Defendants negligently and recklessly failed to disclose to Plaintiff and others important safety and efficacy information about Saxagliptin, thereby suppressing material facts while under a duty to disclose such information.

82. Defendants' representations about the safety and adverse side effects of Saxagliptin were negligently and recklessly made in that Saxagliptin in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

83. Defendants knew or should have known that their representations and omissions were false. Defendants made such false, negligent and reckless representations and omissions with the intent or purpose that Plaintiff and any non-defendant physicians would rely upon such representations, leading to the use of Saxagliptin as described.

84. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Saxagliptin, including serious injury. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Saxagliptin.

85. At the time Defendants made these misrepresentations and/or omissions, they knew or should have known that Saxagliptin was unreasonably dangerous and not what Defendants had represented to Plaintiff, as well as the medical community, the FDA, and the consuming public.

86. Defendants' misrepresentations and/or omissions were undertaken with an intent that doctors and patients, including Plaintiff, rely upon them.

87. Plaintiff and Plaintiff's healthcare providers did not know that these representations were false and justifiably relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Saxagliptin to employ these products.

88. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained injuries and damages.

89. While using Saxagliptin, and as a direct and proximate result thereof, Plaintiff developed serious and/or permanent adverse effects including, but not limited to, heart failure, congestive heart failure, and cardiovascular injury.

90. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

91. Had Plaintiff been aware of the increased risk of side effects associated with Saxagliptin and the relative efficacy of Saxagliptin compared with other readily available products, Plaintiff would not have used these products.

92. Plaintiff's prescribing physicians would not have prescribed Saxagliptin to Plaintiff, would have changed the way in which they treated Plaintiff's relevant conditions, changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of Saxagliptin, and discussed with Plaintiff the true risks of heart failure, congestive heart failure, cardiac failure, and death related to those events, and other serious adverse events had Defendants provided said physicians with an appropriate and adequate information regarding the risks associated with the use of Saxagliptin.

93. Plaintiff's prescribing health care providers were unaware of the true degree, incidence, and risk of heart failure, congestive heart failure, cardiac failure, and death related to those events associated with the use of Saxagliptin, and, if they had been informed, would have used and prescribed alternative therapies to Plaintiff.

94. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, heart failure, congestive heart failure, and a cardiovascular injury, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

95. As a direct and proximate result of Defendants' conduct, Plaintiff incurred obligations and expenses for medical care, testing and treatment. As a direct and proximate result of Defendants' conduct, Plaintiff suffered loss of income, wages, profits and commissions, diminishment of earning potential, and other pecuniary losses.

96. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT III

FAILURE TO WARN

Plaintiff incorporates by reference the factual allegations of this Complaint as though set forth in full in this cause of action and further alleges:

97. Saxagliptin was unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

98. At all relevant and material times, the Defendants designed, manufactured, packaged, marketed, advertised, distributed, and sold Saxagliptin, placing the products into the stream of commerce for sale to, and use by, members of the public, including the Saxagliptin used by Plaintiff.

99. At all relevant and material times, Saxagliptin was designed, manufactured, packaged, marketed, advertised, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

100. The Saxagliptin manufactured by Defendants reached Plaintiff without substantial change and was ingested as directed. The Saxagliptin was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

101. The Plaintiff was administered the Saxagliptin for its intended purpose.

102. Plaintiff used Saxagliptin in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

103. Defendants failed to warn and/or adequately warn Plaintiff, consumers, physicians, and healthcare professionals of the increased health risks associated with using Saxagliptin.

104. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to them.

105. The Plaintiff could not have discovered any defect in the Saxagliptin through the exercise of reasonable care.

106. Defendants, as manufacturers of Saxagliptin, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known those warnings and other clinically relevant information and data, which they distributed regarding the risks of injuries and death associated with the use of Saxagliptin, was incomplete and inadequate.

107. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians. The warnings given by Defendants were inaccurate, unclear, ambiguous, and/or incomplete.

108. Defendants had a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Saxagliptin, as it became or could have become available to Defendants.

109. Defendants marketed, promoted, distributed, and sold unreasonably dangerous and defective prescription Saxagliptin to health care providers empowered to prescribe and dispense to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Defendants misled the medical community about the risk/benefit balance of Saxagliptin, which resulted in injury to Plaintiff.

110. Defendants knew or should have known that Saxagliptin caused unreasonable and dangerous side effects and they continued to promote and market Saxagliptin without stating

safer and more or equally effective alternative drug products existed and/or providing adequate clinically relevant information and data.

111. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury or death as a result of Defendants' conduct.

112. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in at least the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff's physicians to the dangerous risks of Saxagliptin including, among other things, their tendency to increase the risk of, and/or cause, heart failure, congestive heart failure, cardiac failure, and death related to those events;

b. Defendants failed to inform Plaintiff and Plaintiff's physicians that Saxagliptin had not been adequately tested to determine the full extent of the safety risks associated with use of the product;

c. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of heart failure, congestive heart failure, cardiac failure, and death related to those events associated with use of Saxagliptin; and

d. Defendants continued to aggressively promote and sell Saxagliptin even after they knew or should have known of the unreasonable risks of developing heart failure, cardiac failure, and death related to those events from ingestion of Saxagliptin.

113. Defendants and each of them had a duty to warn the FDA, the medical community, Plaintiff, and Plaintiff's physicians about the increased risks of injury, but failed to do so.

114. Defendants had a duty and obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the

adverse health risks associated with exposure to Saxagliptin, and/or that there existed safer and more or equally effective alternative drug products, but failed to do so.

115. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Saxagliptin, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

116. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

117. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff sustained injuries and damages.

118. Plaintiff was prescribed and ingested Saxagliptin manufactured, packaged, marketed, sold and/or distributed by Defendants at various times, which reached Plaintiff without substantial change in the drug's condition.

119. While using Saxagliptin, and as a direct and proximate result thereof, Plaintiff developed serious and/or permanent adverse effects including, but not limited to, heart failure, congestive heart failure, and cardiovascular injury.

120. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses. Plaintiff incurred obligations and expenses for medical care, testing and treatment.

121. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT IV

VIOLATION OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

122. Defendants engaged in unfair and deceptive trade practices with Plaintiff in the following respects:

a. Defendants are merchants, who study, test, design, develop, manufacture, inspect, produce, market, promote, advertise, distribute and/or sell prescription medications, including Onglyza;

b. Defendants knowingly committed unfair and deceptive practices in their study, testing, design, development, manufacture, inspection, production, marketing, promotion, advertising, distribution, and/or sale of Onglyza;

c. Defendants knowingly committed unfair and deceptive practices when they failed to safely design and construct a safe and effective diabetes medication for use by Plaintiff;

d. While Defendants knew or reasonably should have known that Onglyza, when used as prescribed caused a significantly increased risk of injuries, including Congestive Heart Failure, while they were engaged in the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or selling Onglyza, Defendants did not inform the FDA, Plaintiff, and/or Plaintiff's physicians of their knowledge concerning the dangers posed to patients;

e. Defendants failed to give adequate warnings regarding the use and potential problems with Onglyza;

f. Defendant's actions occurred while they were engaged in trade and commerce, and all of the conduct occurred during the course of their business.

123. Defendant's conduct in continuing to market, sell, and distribute Onglyza

without proper warnings after obtaining knowledge that Onglyza caused a significantly increased risk of injuries, including Congestive Heart Failure, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

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

COUNT VI

ALABAMA EXTENDED MANUFACTURERS' LIABILITY

DOCTRINE ALABAMA CODE §§ 6-5-501 *et seq.*

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

124. Defendants are strictly liable to Plaintiff under Ala. Code §§ 6-5-501 *et seq.* ("AEMLD").

125. Defendants have engaged in the business of designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, and/or distribution of Onglyza. Through that conduct, Defendants knowingly and intentionally placed Onglyza into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, who ingested it.

126. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise

released Onglyza into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Onglyza to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of Onglyza.

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

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

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

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

131. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell,

distribute, supply, warn, and take such other steps as necessary to ensure Onglyza did not cause users to suffer from unreasonable and dangerous risks.

132. Defendants negligently and recklessly labeled, distributed, and promoted Onglyza.

133. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Onglyza.

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

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

136. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Onglyza caused serious injuries; they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Onglyza, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

137. Onglyza, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably intended manner without knowledge of this risk of serious bodily

harm.

138. Each of the Defendants knew or should have known that the limited warnings disseminated with Onglyza were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

139. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with the use of Onglyza;

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

c. Failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Onglyza and the comparative severity of such adverse effects;

d. Failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to causing congestion heart failure; and

e. Downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the use of Onglyza.

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

141. Due to these deficiencies and inadequacies, Onglyza was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

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

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

144. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered Congestive Heart Failure and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a

diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

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

PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth here in full and further prays:

145. So far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

a. All available compensatory damages for the described losses with respect to each cause of action;

b. Past and future medical expenses, as well as the cost associated with past and future life care;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress;

e. Consequential damages;

f. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

g. All wrongful death damages permitted by law, where applicable;

h. Disgorgement of profits obtained through unjust enrichment;

i. Restitution;

j. Punitive damages with respect to each cause of action;

k. Reasonable attorneys' fees where recoverable;

l. Costs of this action;

m. Pre-judgment and all other interest recoverable; and

n. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated: December 4, 2017

By: */s/ Bryan F. Aylstock*

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