UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
ROCKINGHAM DIVISION

TERESA ANN FREEMAN, Plaintiff, **v.** BRISTOL-MYERS SQUIBB COMPANY; ASTRAZENECA PHARMACEUTICALS LP; and MCKESSON CORPORATION; Defendants.	**CIVIL ACTION NO: _____** **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Teresa Ann Freeman (also "Plaintiff"), by and through the undersigned counsel, upon information and believe, hereby brings the following allegations and causes of action against Defendants Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff as a direct and proximate cause of taking the prescription drug Kombiglyze XR (also known as Saxagliptin and Metformin HCI extended-release). In support of her Complaint and Jury Demand, Plaintiff alleges 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, Teresa Ann Freeman ("Plaintiff"), by and through Plaintiff's attorneys, Rhine Law Firm, PC and Aylstock, Witkin, Kreis & Overholtz, PLLC, brings this action for personal injuries suffered as a result of being prescribed and ingesting the defective and unreasonably dangerous prescription drug Kombiglyze XR.

6. Kombiglyze XR is prescribed to help lower blood sugar levels in persons with type 2 diabetes mellitus, and at all times relevant hereto, was 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 Kombiglyze XR resulting in injuries.

III. PARTIES

7. At all times relevant to this action, Plaintiff was an individual, citizen and resident of Star, North Carolina.

8. Upon information and belief, Plaintiff ingested Kombiglyze XR from approximately November 2013 to October 2014, 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 Kombiglyze XR within the United States including in the state of North Carolina.

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 Kombiglyze XR within the United States including in the state of North Carolina.

11. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California 94104. At all relevant times, McKesson has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling and marketing of Kombiglyze XR within the United States including in the state of North Carolina.

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 Kombiglyze XR 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 Kombiglyze XR from the public, Plaintiff, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to those treated with Kombiglyze XR, including Plaintiff. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiff would not have ingested Kombiglyze XR.

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 Kombiglyze XR.

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

17. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to each 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 USC § 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 North Carolina. Defendants have committed a tort in whole or in part in the state of North Carolina and have regular and continuing contacts with the state of North Carolina.

21. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including Kombiglyze XR, within the state of North Carolina, with a reasonable expectation that Kombiglyze XR products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

22. At all times relevant to this action, Defendants were engaged in substantial business activities in the state of North Carolina, including disseminating inaccurate, false, and misleading information about Kombiglyze XR to health care professionals in North Carolina with a reasonable expectation that such information would be used and

relied upon by health care professionals throughout North Carolina and throughout the United States.

23. At all relevant times, Defendants transacted, solicited, and conducted business in the state of North Carolina through their employees, agents, and/or sales representatives and derived substantial revenue from such business in the state of North Carolina.

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

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

V. FACTUAL ALLEGATIONS

26. 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.

27. 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.

28. 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.

29. 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.

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

[1] *Id.*

31. 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.

32. 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.

33. 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.

[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-

34. 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.

35. 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.

36. 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.

37. 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.

38. 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

39. From on or about November 2013 until October 2014, Plaintiff ingested Kombiglyze XR that she was prescribed by her physicians in Star, North Carolina, including, but not limited to Janet L. Britt, PA-C, Michael McLeod, M.D., and Krystal Richardson, PA (now Krystal R. Wright, PA).

40. On February 3, 2015, Plaintiff began experiencing significant shortness of breath. She had been experiencing intermittent difficulty breathing for several weeks. Plaintiff presented to the emergency room at FirstHealth Richmond Memorial Hospital experiencing respiratory distress. Unfortunately, Richmond Memorial could not perform a chest CTA because of a non-working CT scanner. Ms. Freeman had to be transferred to FirstHealth Moore Regional Hospital where a CTA was performed. Whereupon she was then transferred back to Richmond Memorial and was admitted to ICU. She was diagnosed with acute left-sided systolic congestive heart failure.

41. Presently, she continues to treat for her injuries that resulted from her congestive heart failure, which was, in turn, caused by her ingestion of Kombiglyze XR.

42. Plaintiff reviewed package inserts and labeling provided and created by Defendants for Kombiglyze XR at the time that she purchased the product, and she relied upon the information contained therein when deciding to ingest and continue ingesting the product.

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

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

45. 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.

46. At all relevant times, Defendants had knowledge that there was a significant increased risk of adverse events associated with Kombiglyze XR 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.

47. 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 Kombiglyze XR including but not limited to heart failure, congestive heart failure, cardiac failure, and death related to those events.

48. On information and belief, Plaintiff's prescribing physicians would not have prescribed Kombiglyze XR 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 Kombiglyze XR, 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 Kombiglyze XR.

49. 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 Kombiglyze XR, and, if they had been informed, would have used and prescribed alternative therapies to Plaintiff.

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

51. 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.

52. 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.

53. As part of their duty to exercise reasonable care, Defendants were obligated to follow public laws and regulations enacted and promulgated to protect the safety of persons such as plaintiff, including 21 U.S.C. §§ 331(a) & 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

54. The labeling, including package inserts, for Saxagliptin failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (t), and the requirements of 21 C.F. R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

55. Specifically, the product label and package insert for Saxagliptin is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe Saxagliptin.

56. Saxagliptin is misbranded pursuant to 21 U.S.C. § 352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

57. Because the Defendants had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand Saxagliptin, and because it violated the duty, Defendants are guilty of negligence per se.

58. Saxagliptin is further misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

59. Defendants also violated 21 C.F.R. § 201.57 because it failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Saxagliptin.

60. Saxagliptin is mislabeled pursuant to 21 C.F.R. § 201.57 because Defendants did not revise the labeling to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., risk of Heart Failure and Congestive Heart Failure).

61. Saxagliptin violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

62. Saxagliptin violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

VII. DELAYED DISCOVERY

63. 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.

64. 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.

65. 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.

66. Indeed, Plaintiff had no knowledge, nor any reason to gain knowledge of the relationship between heart failure and Saxagliptin no earlier than on or around late March 2016 when she first learned others were filing lawsuits based on allegations similar to those alleged herein.

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

68. 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
NEGLIGENCE

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:

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

70. 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.

71. 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 by 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, despite the existence of a safer alternative design.[3]

[3] Januvia and Janumet existed as a safer alternative design available prior to the approval of Saxagliptin given it is available with a similar administration method, treats the same condition and the manufacturer completed a cardiovascular outcomes trial in which no Heart Failure signal was observed.

i. Failing to use reasonable care in the design and development of Saxagliptin, considering that:

i. 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;

ii. Saxagliptin was not safe because the health risks associated with each product outweighed any benefit of the drug and there are no patients for whom the benefit of Saxagliptin outweighed the risks;

iii. Saxagliptin was insufficiently and/or inadequately tested by Defendants;

iv. 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;

j. 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;

k. Failing to accompany Saxagliptin with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects, inclusive of those alleged herein. Specifically, Defendants were further negligent in providing adequate warnings by:

i. Failing 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;

ii. Failing 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;

iii. Failing 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

iv. Continuing 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.

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

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

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

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

p. 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;

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

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

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

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

82. 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.

83. 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.

84. 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.

85. 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.

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

COUNT II
NEGLIGENCE PER SE

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:

86. At all relevant times, Defendants had a duty to exercise reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, sell, prescribe and adequately warn of the risks and dangers of Saxagliptin, including a duty to assure that the product did not cause unreasonable, dangerous side-effects to users.

87. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling Saxagliptin.

88. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of Saxagliptin to Congestive Heart Failure and the life threatening complications of this condition.

89. Defendants had a duty to accurately communicate the risks and benefits of Saxagliptin to physicians, healthcare provides, and patients.

90. Defendants failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Saxagliptin into interstate commerce in that Defendants knew or should have known that using created an unreasonable risk of dangerous injuries including Congestive Heart Failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

91. 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.

92. Defendants, their agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128.

93. The laws violated by Defendants were designed to protect Ms. Freeman and similarly situated persons against the risks and hazards that have actualized in this case. Therefore, Defendants' conduct constitutes negligence per se.

94. Despite the fact that Defendants knew or should have known that Saxagliptin significantly increased the risk of injuries, including Congestive Heart Failure, Defendants continued and continue to negligently and misleadingly market, manufacture, distribute, and/or sell Saxagliptin to consumers, including Ms. Freeman.

95. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Saxagliptin to cause or increase the harm of Congestive Heart Failure, and the life threatening complications of this condition.

96. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Ms. Freeman suffered and/or will continue to suffer.

97. Had Ms. Freeman not taken Kombiglyze XR, she would not have suffered the injuries and damages as described herein.

98. As a result of the foregoing acts and omissions, Ms. Freeman was caused to suffer serious injuries, including Congestive Heart Failure, and other injuries that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring, and/or medications.

99. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including Congestive Heart Failure, and these injuries were foreseeable.

100. Ms. Freeman also has sustained severe emotional distress and suffering as a result Defendants' wrongful conduct.

101. Ms. Freeman did not know the nature and extent of the injuries that could result from Kombiglyze XR and was misinformed about the benefits of Kombiglyze XR and could not have discovered this information independently.

102. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging,

preparing for use, and selling Saxagliptin, and failing to adequately test and warn of the risks and dangers of Saxagliptin.

103. Despite the fact that Defendants knew or should have known that Saxagliptin caused unreasonable, dangerous side effects, Defendants continued to market Saxagliptin to consumers including Ms. Freeman, when there were safer alternative methods available.

104. Defendants' negligence was a foreseeable and proximate cause of the Plaintiff's injuries, harm and economic loss which she suffered, and will continue to suffer, as described and prayed for herein.

105. Defendants failed to exercise ordinary care in the sale, warnings, quality assurance, quality control, distribution, advertising, promotion, sale and marketing of Saxagliptin in that Defendants knew or should have known that the drug created a high risk of unreasonable harm.

106. Defendants were negligent in the advertising, warning, marketing and sale of Saxagliptin in that, among other things, they:

a. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Saxagliptin;

b. Negligently failing to adequately and correctly warn Ms. Freeman, the public, the medical and healthcare profession, and FDA of the dangers of Saxagliptin;

c. Failed to accompany their product with accurate warnings regarding the risk of all possible adverse side effects concerning Saxagliptin;

d. Failed to warn Ms. Freeman and/or Ms. Freeman's healthcare providers of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

e. Placed an unsafe product into the stream of commerce;

f. Over-promoted Saxagliptin and marketed and advertised the drug in a manner that minimized the risks and damages of the drug; and,

g. Were otherwise careless or negligent.

107. Despite the fact that Defendants knew or should have known that Saxagliptin caused unreasonable, dangerous side-effects which many users would be unable to remedy, Defendants continued to market Saxagliptin to consumers, including the medical community and Ms. Freeman.

108. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Ms. Freeman, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to re-label, warn, or inform the unsuspecting consuming public.

109. Defendants knew or should have known that consumers such as Ms. Freeman would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

110. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

111. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles regardless of whether arising under statute and/or common law.

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

COUNT III
VIOLATION OF THE NORTH CAROLINA UNFAIR AND 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:

112. By reason of the conduct as alleged herein, and by inducing Plaintiff and Plaintiff's physicians to use Saxagliptin through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices, and the concealment and suppression of material facts including, but not limited to, fraudulent statements, concealments, and misrepresentations identified herein and above, Defendants violated the provisions of N.C. Gen. Stat. § 75-1.1 et. seq.

113. Defendants engaged in unfair and deceptive trade practices with Ms. Freeman 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 Saxagliptin;

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 Saxagliptin;

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 Ms. Freeman;

d. While Defendants knew or reasonably should have known that Saxagliptin, 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 Saxagliptin, Defendants did not inform the FDA, Ms. Freeman, and/or Ms. Freeman'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 Saxagliptin;

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.

114. As a direct and proximate result of Defendants' statutory violations, Plaintiff was damaged by Saxagliptin which would not have occurred had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices, and the concealment and suppression of material facts to induce Plaintiff and Plaintiff's physicians to use this product.

115. By reason of such violations and pursuant to N.C. Gen. Stat. § 75-1.1 et. seq. Plaintiff is entitled to recover all of the monies paid for Saxagliptin; to be compensated for the cost of the medical care arising out of the use of Saxagliptin; and to recover any and all consequential damages recoverable under the law including, but not limited to, gambling losses, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress.

116. Plaintiff is entitled to seek compensatory damages, attorney's fees, and other remedies as determined by the Court pursuant to N.C. Gen. Stat. § 75-1.1 et. seq.

117. Defendants' actions occurred in the course of and have significant effects upon commerce.

118. Defendants' actions are substantially injurious to consumers, offend established public policy, are immoral, oppressive, and unscrupulous.

119. Plaintiff reasonably and justifiably relied upon Defendants' actions and practices to Plaintiff's detriment.

120. Defendants actions constitute Unfair and Deceptive Trade Practices bylaw, and subject them to assessment of attorneys' fees, costs, and trembling of all damages awarded against them.

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

COUNT IV
FAILURE TO WARN

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:

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

122. 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.

123. 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.

124. 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.

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

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

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

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

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

130. 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 that 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.

131. 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.

132. 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.

133. 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.

134. 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.

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

136. 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.

137. 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.

138. 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.

139. 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.

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

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

142. 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.

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's also demands that the issues contained herein be tried by a jury

COUNT V
BREACH OF WARRANTY OF MERCHANTABILITY

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:

143. At all times mentioned in this Complaint, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold Saxagliptin, and prior to the time it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff, and Plaintiff's physicians and healthcare providers, that Saxagliptin was of merchantable quality and safe for the use for which it was intended.

144. Defendants knew and intended that Saxagliptin be used by Plaintiff and other consumers when the products were placed into the stream of commerce.

145. Defendants knew of the use for which Saxagliptin was intended and impliedly warranted Saxagliptin to be of merchantable quality and safe and fit for their intended use.

146. Plaintiff and her healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants, and upon the express and/or implied warranty that Saxagliptin was safe, of merchantable quality, and fit for use by Plaintiff and other consumers.

147. The Saxagliptin used by Plaintiff was not safe, of merchantable quality, or fit for its intended use.

148. The product was unsafe for its intended use and was not of merchantable quality, as warranted by Defendants, in that Saxagliptin had very dangerous propensities when put to its intended use and would cause severe injury (or death) to the user. Saxagliptin was unaccompanied by adequate warnings of their dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

149. The Saxagliptin used by Plaintiff was neither safe nor fit for use because Saxagliptin products were and are unreasonably dangerous and unfit for the ordinary purposes for which they are used.

150. As a direct and proximate result of the breach of warranty of merchantability by Defendants, Plaintiff sustained injuries and damages.

151. 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.

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's also demands that the issues contained herein be tried by a jury.

COUNT VI
BREACH OF EXPRESS WARRANTY

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:

152. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of Saxagliptin was expressly warranted to be safe for use by Plaintiff and other members of the general public.

153. Defendants expressly represented to Plaintiff, consumers and the medical community that Saxagliptin was:

a. safe;

b. efficacious;

c. fit for use in persons with Type 2 diabetes mellitus;

d. of merchantable quality;

e. adequately tested;

f. well tolerated in adequate and well-controlled clinical studies; and

g. did not increase the risk of experiencing serious, life threatening side effects.

154. Defendants breached those express warranties as follows:

a. Defendants misrepresented the safety of Saxagliptin in its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;

b. Defendants misrepresented the risks associated with using Saxagliptin;

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury;

d. Defendants misrepresented that Saxagliptin was as safe or safer than other available forms of treatment for Plaintiff's conditions; and

e. Saxagliptin was unaccompanied by adequate warnings of its dangerous propensities that were either known or knowable at the time of distribution.

155. Saxagliptin did not conform to Defendants' express representations and warranties.

156. At all relevant times, Saxagliptin did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

157. At all relevant times, Saxagliptin did not perform in accordance with the Defendants' representations because Saxagliptin is not safe and causes high levels of serious side effects.

158. In deciding to purchase and use Saxagliptin, Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

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

160. 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.

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's also demands that the issues contained herein be tried by a jury.

COUNT VII
BREACH OF IMPLIED WARRANTY

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:

161. At all relevant and material times, Defendants manufactured, distributed, advertised, and sold Saxagliptin.

162. Defendants impliedly warranted to Plaintiff that Saxagliptin was safe for use by Plaintiff's and the consuming population.

163. Defendants knew and intended that Saxagliptin be used in treatment for persons with Type 2 diabetes mellitus when the products were placed into the stream of commerce.

164. Plaintiff and Plaintiff's healthcare providers used Saxagliptin as intended and directed by the Defendants, and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

165. Plaintiff was a foreseeable user of Defendants' product, Saxagliptin. Saxagliptin was expected to reach, and did in fact reach, Plaintiff without substantial change in the condition in which the products were manufactured and sold by Defendants.

166. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants, and upon the Defendants' implied warranty that Saxagliptin was safe, of merchantable quality, and fit for use.

167. The Saxagliptin used by Plaintiff was not safe, of merchantable quality, nor fit for use.

168. The Saxagliptin used by Plaintiff did not perform in accordance with Defendants' representations because Saxagliptin is not safe and causes high levels of serious, life-threatening side effects.

169. Defendants breached the implied warranty in that Saxagliptin did not conform to Defendants' representations.

170. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts described herein, Plaintiff sustained injuries and damages.

171. 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.

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's also demands that the issues contained herein be tried by a jury.

COUNT VIII
FRAUDULENT MISREPRESENTATION

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:

172. Defendants made fraudulent misrepresentations with respect to Saxagliptin in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Saxagliptin had been tested and found to be safe and effective for the treatment of diabetes; and

b. upon information and belief, Defendants represented that Saxagliptin was safer than other alternative medications.

173. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of Saxagliptin to Ms. Freeman, other consumers, Ms. Freeman's physicians, and the medical community.

174. The representations were made by the Defendants with the intent that doctors and patients, including Ms. Freeman and Ms. Freeman's physicians, rely upon them.

175. Defendants' representations were made with the intent of defrauding and deceiving Ms. Freeman, other consumers, Ms. Freeman's physicians, and the medical community to induce and encourage the sale of Saxagliptin.

176. Ms. Freeman, Ms. Freeman's doctors, and others relied upon these representations.

177. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ms. Freeman suffered Congestive Heart Failure and other related health complications. In addition, Ms. Freeman requires and will continue to require healthcare and services.

178. Ms. Freeman has incurred and will continue to incur medical and related expenses. Ms. Freeman 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. Ms. Freeman has incurred and will continue to incur mental and physical pain and suffering.

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

COUNT IX
NEGLIGENT MISREPRESENTATION

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:

179. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning Saxagliptin, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

180. Defendants disseminated to health care professionals and consumers – through published labels, marketing materials, and otherwise – information that misrepresented the properties and effects of Saxagliptin with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest Saxagliptin.

181. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Saxagliptin, knew or reasonably should have known that health care professionals and consumers of Saxagliptin rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting Saxagliptin.

182. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Saxagliptin were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Ms. Freeman.

183. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of Saxagliptin, knew or reasonably should have known that health care professionals would write prescriptions for Saxagliptin in reliance on the information

disseminated by Defendants, and that the patients receiving prescriptions for Saxagliptin would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon by health care professionals and consumers, including Ms. Freeman, was materially inaccurate, misleading, or otherwise false.

184. From the time Saxagliptin was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of Saxagliptin. Defendants made material misrepresentations to Ms. Freeman, Ms. Freeman's health care professionals, the healthcare community, and the general public, including:

a. Stating that Saxagliptin had been tested and found to be safe and effective for the treatment of diabetes;

b. Concealing, misrepresenting, and actively downplaying the severe and life threatening risks of harm to users of Saxagliptin, when compared to comparable or superior alternative pharmaceutical therapies; and

c. Misrepresenting Saxagliptin's risk of unreasonable and dangerous, adverse side effects.

185. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

186. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

187. Defendants made these representations with the intent to induce reliance thereon, and to encourage prescription, purchase, and use of Saxagliptin.

188. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Ms. Freeman, the truth regarding Defendants' claims that Saxagliptin had been tested and found to be safe and effective for treating diabetes.

189. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

190. Defendants failed to exercise ordinary care in making their representations concerning Saxagliptin and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of Saxagliptin.

191. Defendants engaged in a nationwide marketing campaign, over-promoting Saxagliptin in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over promotion was undertaken by touting the safety and efficacy of Saxagliptin while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of Saxagliptin, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented Saxagliptin's risk of unreasonable and dangerous adverse side effects.

192. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Saxagliptin, including Ms. Freeman. Defendants had knowledge of the safety problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

193. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ms. Freeman suffered Congestive Heart Failure and other related health complications. In addition, Ms. Freeman requires and will continue to require healthcare and services.

194. Ms. Freeman has incurred and will continue to incur medical and related expenses. Ms. Freeman 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. Ms. Freeman has incurred and will continue to incur mental and physical pain and suffering.

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

COUNT X
FRAUDULENT CONCEALMENT

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:

195. Throughout the relevant time period, Defendants knew that Saxagliptin was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of Saxagliptin.

196. Defendants fraudulently concealed information with respect to Saxagliptin in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submission that Saxagliptin was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using Saxagliptin; and

b. Upon information and belief, Defendants represented that Saxagliptin was safer than other alternative medications and fraudulently concealed information which demonstrated that Saxagliptin was not safer than alternatives available on the market.

197. Defendants were under a duty to Ms. Freeman to disclose and warn of the defective and dangerous nature of Saxagliptin because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of Saxagliptin;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of Saxagliptin in the documents

and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of Saxagliptin from Ms. Freeman.

198. As the designers, manufacturers, sellers, promoters, and/or distributors of Saxagliptin, Defendants had unique knowledge and special expertise regarding Saxagliptin. This placed them in a position of superiority and influence over Ms. Freeman and her healthcare providers. As such, Ms. Freeman and Ms. Freeman's health care providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

199. The facts concealed or not disclosed by Defendants to Ms. Freeman were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use Saxagliptin.

200. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by Saxagliptin was intentional, and the representations made by Defendants were known by them to be false.

201. The concealment of information and the misrepresentations about Saxagliptin were made by Defendants with the intent that doctors and patients, including Ms. Freeman, rely upon them so that Ms. Freeman would request and purchase Saxagliptin and Ms. Freeman's health care providers would prescribe and recommend Saxagliptin.

202. Ms. Freeman, Ms. Freeman's doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by Saxagliptin.

203. Had Defendants not concealed or suppressed information regarding the severity of the risks of Saxagliptin, Ms. Freeman's physicians would not have prescribed, and Ms. Freeman would not have ingested, the drug.

204. Defendants, by concealment or other action, intentionally prevented Ms. Freeman and her health care professionals from acquiring material information regarding the lack of safety of Saxagliptin, thereby preventing Ms. Freeman from discovering the truth. As such, Defendants are liable for fraudulent concealment.

205. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ms. Freeman suffered Congestive Heart Failure and other related health complications. In addition, Ms. Freeman requires and will continue to require healthcare and services.

206. Ms. Freeman has incurred and will continue to incur medical and related expenses. Ms. Freeman 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. Ms. Freeman has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully request 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 XI
FRAUD

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:

207. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Ms. Freeman, Ms. Freeman's prescribing health care professionals, the health care industry and consumers that Saxagliptin had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

208. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risks of adverse health events associated with the use of Saxagliptin. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of Saxagliptin, such as Ms. Freeman.

209. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Ms. Freeman and her prescribing health care professionals, so as to induce them to recommend, prescribe, disperse, or purchase Saxagliptin, despite the risk of severe life threatening injuries, which Defendants knew were caused by the product.

210. The Defendants fraudulently and intentionally concealed material information, as aforesaid, Defendants knew that Saxagliptin was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risk.

211. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of Saxagliptin.

212. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with Saxagliptin from physicians and patients, including Ms. Freeman and her prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of Saxagliptin. For example:

a. Saxagliptin was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of Saxagliptin does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of Saxagliptin were greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with Saxagliptin was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

213. Defendants knew that the risks of harm associated with the use of Saxagliptin was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Ms. Freeman relied when ingesting Saxagliptin;

a. The limited clinical testing revealed that Saxagliptin had an unreasonably high risk of injury, including Ms. Freeman's injuries, above and beyond those associated with other diabetes drug therapies;

b. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

c. Defendants had knowledge of the dangers involved with the use of Saxagliptin, which dangers were greater than those associated with other diabetes drug therapies; and

d. Defendants intentionally and knowingly failed to disclose that patients using Saxagliptin could suffer Congestive Heart Failure; and/or Saxagliptin was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

214. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest Saxagliptin, information that was not publicly disseminated or made available, but instead was actively suppressed by Defendants.

215. Defendants' intentional concealment and omissions of material fact concerning the safety of Saxagliptin was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Ms. Freeman, and with reckless intent to mislead, so as to cause Ms. Freeman's prescribing physicians to purchase, prescribe, and/or dispense Saxagliptin, and to cause Ms. Freeman to rely on Defendants' fraudulent misrepresentations that Saxagliptin was a safe and effective diabetes drug therapy.

216. At the time Ms. Freeman purchased and used Saxagliptin, Ms. Freeman was unaware that Defendants had made misrepresentations and omissions, and instead Ms. Freeman reasonably believed Defendants' representations to constitute a true, complete, and accurate portrayal of Saxagliptin's safety and efficacy.

217. Defendants knew and had reason to know that Saxagliptin could and would cause serious personal injury to the users of the product, and that the product was inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

218. In reliance on Defendants' false and fraudulent misrepresentations, Ms. Freeman was induced to use and in fact used Saxagliptin, thereby sustaining injuries and damages. Defendants knew and had reason to know that Ms. Freeman and her health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Ms. Freeman and her health care professionals would not have prescribed and ingested Saxagliptin if the true facts regarding the drug had not been concealed by Defendants.

219. During the marketing and promotion of Saxagliptin to health care professionals, neither Defendants nor the co-promoters who were dealing Saxagliptin on Defendants' behalf, warned health care professionals, including Ms. Freeman's prescribing health care professional, that Saxagliptin caused or increased the risk of harm of Congestive Heart Failure.

220. Ms. Freeman reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was crucial to understanding the true dangers inherent in the use of Saxagliptin.

221. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Ms. Freeman, the public, Ms. Freeman's health care professionals, and the health care industry that Saxagliptin was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

222. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of Saxagliptin, including Ms. Freeman. Defendants knew of Saxagliptin's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

223. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Ms. Freeman suffered Congestive Heart Failure and other related health complications. In addition, Ms. Freeman requires and will continue to require healthcare and services.

224. Ms. Freeman has incurred 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. Ms. Freeman's direct medical losses and costs include physician care, monitoring and treatment. Ms. Freeman 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's also demands that the issues contained herein be tried by a jury.

IX. REQUEST FOR PUNITIVE DAMAGES

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:

225. At all times relevant herein, Defendants:

a. knew that Saxagliptin was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Saxagliptin;

d. with full knowledge of the health risks associated with Saxagliptin and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed Saxagliptin for routine use.

226. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.

227. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

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's also demands that the issues contained herein be tried by a jury.

X. PRAYER FOR RELIEF

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

228. 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 damages 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.

XI. DEMAND FOR JURY TRIAL

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

Dated: January 23, 2018

RESPECTFULLY SUBMITTED,

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Motion for Pro Hac Vice to be Filed