UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

IN RE: ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE XR (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION	Master File No. 5:18-md-2809-KKC **MDL No. 2809**
THIS DOCUMENT RELATES TO: BOBBIE JEAN SINGLETARY, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY; ASTRAZENECA PHARMACEUTICALS, LP; MCKESSON CORPORATION; Defendants	Case No.: **COMPLAINT FOR DAMAGES** JURY TRIAL DEMANDED

Plaintiff, Bobbie Jean Singletary, by counsel, alleges against Defendants, Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation (collectively, the "Defendants"), as follows:

I. INTRODUCTION

1. This is an action for damages relating to the Defendants' design, manufacture, sale, marketing, advertising, promotion, testing, 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, Bobbie Jean Singletary ("Plaintiff"), by counsel, 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.

II. PARTIES

5. Plaintiff, Bobbie Jean Singletary, is and, at all relevant times, was a citizen and resident of Concord, Cabarrus County, North Carolina.

6. Plaintiff's physician prescribed Onglyza to her on May 10, 2013 and she took it as instructed from May 10, 2013 to approximately May 7, 2016 resulting in severe and permanent injuries. Specifically, while taking Onglyza, on approximately February 25, 2014, Plaintiff's physician diagnosed her with heart failure.

7. Defendant, Bristol-Myers Squibb Company ("BMS"), is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York 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 North Carolina. Pursuant to the Stipulated Order regarding Direct Filing and Service of Complaints (Dkt. 174), service shall be effective upon BMS by serving a copy of this complaint by e-mail to OnglyzaMDL@bms.com.

8. Defendant, AstraZeneca Pharmaceuticals, LP ("AZ"), is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 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

North Carolina. Pursuant to the Stipulated Order regarding Direct Filing and Service of Complaints (Dkt. 174), service shall be effective upon AZ by serving a copy of this complaint by e-mail to OnglyzaMDL@astraseneca.com.

9. 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 Saxagliptin within the state of North Carolina. Pursuant to the Stipulated Order regarding Direct Filing and Service of Complaints (Dkt. 174), service shall be effective upon McKesson by serving a copy of this complaint, along with the Waiver of Service of Summons form, by U.S. mail to McKesson Corporation, c/o Emily Ullman, Covington & Burling LLP, One City Center, 850 Tenth Street, NW, Washington, DC 20001-4956.

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

11. 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.

12. 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.

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

14. 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.

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

III. JURISDICTION AND VENUE

16. This matter is directly filed in the United States District Court for the Eastern District of Kentucky pursuant to this Court's Order regarding Direct Filing and Service of Complaints (Dkt. 174) filed in MDL No. 2809, *In Re: Onglyza (Saxagliptin) and Kombiglyze XR (Saxagliptin and Metformin) Products Liability Litigation*, otherwise Plaintiff would have filed her Complaint in the U.S. District Court for the Middle District of North Carolina, Winston-Salem Division.

17. This Court has original jurisdiction 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.

18. Venue is proper for pre-trial purposes in the Eastern District of Kentucky, in accordance with this Court's Order Regarding Direct Filing and Service of Complaints (Dkt. 174). Prior to trial, Plaintiffs may seek a transfer to her federal district of residence, the Middle District of North Carolina, Winston-Salem Division, unless otherwise agreed to by the parties.

IV. FACTUAL ALLEGATIONS

19. 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.

20. Saxagliptin works by inhibiting the proteolytic activity of DPP4, thereby potentiating the action of Glucagon-like peptide-1 (GLP-1), an antihyperglycemic 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.

21. 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 their 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.

22. 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. 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.

23. 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.

24. 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.

25. 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.

26. 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.[1]

27. On April 5, 2016, the FDA announced that its safety review found that type 2 diabetes medicines containing Saxagliptin and Alogliptin may increase the risk of heart failure,

[1] 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-

particularly in patients who already have heart or kidney disease. The FDA then ordered new warnings be added to the drug labels about this safety issue.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

IV. PLAINTIFF'S USE OF SAXAGLIPTIN

34. Plaintiff was prescribed and ingested Saxagliptin. Specifically, Plaintiff Bobbie Jean Singletary was prescribed and ingested Onglyza beginning approximately May 10, 2013, through approximately May 7, 2016 as part of her treatment for type 2 diabetes.

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

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

37. 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.

38. 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.

39. 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.

40. Upon 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.

41. Upon 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.

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

43. 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.

44. 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.

V. DELAYED DISCOVERY

45. 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.

46. 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.

47. 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.

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

49. 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.

CAUSES OF ACTION

COUNT I
DESIGN DEFECT

50. 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:

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 the 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 an express warranty of the manufacturer about 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. Defendants thus acted with conscious and deliberate disregard of the foreseeable harm caused by Saxagliptin.

59. 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.

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

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

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

63. 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 including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

64. 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

65. 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:

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

67. 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.

68. 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;

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.

69. 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.

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

71. 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.

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

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

80. 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.

81. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained severe and permanent injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

82. 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.

83. 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

84. 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:

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

86. 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.

87. 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.

88. 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.

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

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

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

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

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

94. 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.

95. 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.

96. 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.

97. 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.

98. 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.

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

100. 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 Saxigliptin 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.

101. 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.

102. 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.

103. 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.

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

105. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff sustained injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

106. 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
BREACH OF WARRANTY OF MERCHANTABILITY

107. 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:

108. 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.

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

110. 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.

111. Plaintiff and their 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.

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

113. 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.

114. 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.

115. As a direct and proximate result of the breach of warranty of merchantability by Defendants, Plaintiff sustained severe and permanent injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

116. 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 V
BREACH OF EXPRESS WARRANTY

117. 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:

118. 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.

119. 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.

120. 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.

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

122. 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.

123. 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.

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

125. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained severe and permanent injuries and damages including but not limited to physical injury, past and

future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

126. 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 VI
BREACH OF IMPLIED WARRANTY

127. 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:

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

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

130. 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.

131. 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.

132. 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.

133. 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.

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

135. 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.

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

137. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations, and otherwise culpable acts described herein, Plaintiff sustained severe and permanent injuries and damages including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future.

138. 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 VII
VIOLATION OF THE NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT

139. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

140. Defendants are liable to Plaintiff pursuant to the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.* (hereinafter, "DTPA"). Defendants are in the business of manufacturing, distributing, selling, and marketing Saxagliptin. Defendants and/or their agents designed, formulated, manufactured, assembled, prepared for sale,

distributed, and/or sold the drugs to Plaintiff in a defective condition unreasonably dangerous when used as intended in the usual and customary manner.

141. At all times mentioned, Defendants' conduct was in violation of the DTPA in that Defendants' conduct constitutes business practices, which are unfair, false, misleading, and deceptive.

142. Privity existed between Plaintiff and Defendants.

143. Plaintiff, Bobbie Jean Singletary, while consuming Saxagliptin in the usual and customary manner as intended, suffered injury as a proximate result of Defendants placing the products on the market, Defendants' use of false and/or misleading misrepresentations and/or omissions of material fact in connection with the marketing, promotion, and sale of Saxagliptin. Defendants communicated the purported benefits of Saxagliptin while failing to disclose the serious and dangerous injuries related to the use of the products, with the intent that the consumers, such as Plaintiff, would rely upon the misrepresentations and purchase and use Saxagliptin believing it to be safe and beneficial for use in the prescribed, usual and customary manner.

144. The Saxagliptin was unreasonably dangerous and defective at the time Defendants placed it on the market, and at the time of Plaintiff's consumption and injuries, was in substantially the same condition as it was at the time the Saxagliptin were marketed by Defendants.

145. Defendants' violation of the DTPA is a substantial factor in causing the Plaintiff to endure great mental pain and anguish, humiliation, mortification, and has further caused the Plaintiff to incur substantial pecuniary loss. Plaintiff has further been caused to incur attorneys' fees as a result of the Defendants' conduct.

146. Defendants acted towards the Plaintiff with reckless disregard of the Plaintiff's rights, thereby entitling the Plaintiff to punitive damages.

147. As a direct and proximate result of the Defendant's violations of the DTPA, Plaintiff has suffered significant and permanent damages, including but not limited to physical injury, past and future medical expenses, lost income, loss of earning capacity, past and future physical and mental pain and suffering, and will continue to suffer all such damages in the future. Additionally, Plaintiffs are entitled to recover attorney's fees and punitive damages.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff, Bobbie Jean Singletary, demands:

1. Judgment against Defendants, Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation for compensatory damages in an amount in excess of the amount necessary to invoke the jurisdiction of this Court and reasonably calculated to compensate the Plaintiff for her damages;
2. Punitive damages against the Defendants, Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, and McKesson Corporation;
3. Attorneys' fees;
4. Costs of this action;
5. Pre-judgment and all other interest recoverable; and
6. 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: November 5, 2018

Respectfully Submitted,

/s/ Jennifer A. Moore

Jennifer A. Moore
Ashton Rose Smith
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JS 44 (Rev. 11/15)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Bobbie Jean Singletary

(b) County of Residence of First Listed Plaintiff Mecklenburg (NC)
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jennifer A. Moore, Ashton Rose Smith
Grossman & Moore, PLLC, 401 West Main Street, Suite 1810, Louisville, KY 40202; ph: (502) 657-7100

DEFENDANTS

Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals, LP, McKesson Corp.

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

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

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Defective pharmaceutical drug Onglyza

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Karen K. Caldwell DOCKET NUMBER 5:18-md-2809-KKC

DATE 11/05/2018

SIGNATURE OF ATTORNEY OF RECORD Jennifer A. Moore

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.