**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO**
**EASTERN DIVISION AT COLUMBUS**

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| PHYLLIS MARCUM, ON BEHALF OF THE ESTATE OF CHARLES MARCUM, | ) | Case No. |
| Plaintiff, | ) | |
| v. | ) | |
| BRISTOL-MYERS SQUIBB COMPANY; ASTRAZENECA PHARMACEUTICALS LP; | ) | |
| Defendants | | |

**COMPLAINT**

Plaintiff Phyllis Marcum ("Plaintiff"), on behalf of the estate of Charles Marcum, hereby files this Complaint and Jury Demand against Defendants for personal injuries suffered from the consumption of Saxagliptin pharmaceutical products, sold under the brand name Onglyza and/or Kombiglyze XR.

**PARTIES**

1. Plaintiff, Phyllis Marcum, individually and as Personal Representative on behalf of the estate of Charles Marcum, by and through Plaintiff's attorneys, brings this action for personal injuries suffered by Charles Marcum as a result of being prescribed and ingesting the defective and unreasonably dangerous prescription drug(s) Onglyza and/or Kombiglyze XR.

2. As used herein, "Plaintiff" shall mean to refer to the Plaintiff identified herein as Phyllis Marcum, the surviving spouse of the Decedent. As used herein, "Decedent" shall refer to the deceased ingesting Plaintiff, Charles Marcum.

3. At the time of Decedent's ingestion of and injuries related to Onglyza and/or Kombiglyze XR, Plaintiff and Decedent were residents and citizens of Pickerington, Ohio, which is located in Fairfield County, Ohio. Plaintiff currently resides in Gulfport, Florida.

4. 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 regularly and continuously did business within the Southern District of Ohio, including manufacturing, labeling, packaging, marketing, advertising, distributing and selling Saxagliptin.

5. Defendant AstraZeneca Pharmaceuticals LP ("AZ") is a limited partnership organized under the laws of Delaware, with its principal registered office at 1800 Concord Pike, Wilmington, DE 19850. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a Swedish corporation with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's limited partner is Zeneca, Inc., a Delaware corporation with its principal place of business in Delaware. AstraZeneca PLC is a publicly-traded company and is, indirectly, the ultimate parent of AstraZeneca Pharmaceutical LP. At all relevant times, AZ regularly and continuously did business within the Southern District of Ohio including manufacturing, labeling, packaging, marketing, advertising, distributing and selling Saxagliptin.

6. Defendants are in the business of designing, manufacturing, marketing, selling and distributing Saxagliptin and Onglyza, including in Ohio.

## JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal place of business in states other than the state in which the Plaintiff resides.

8. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in this District, and because Defendants conduct substantial business in this District. Fairfield County, where Plaintiff and Decedent resided at the time of Decedent's injury that is the subject of this complaint, is furthermore part of the Southern District of Ohio.

10. This Court has personal jurisdiction over the Defendants because they have done business in the State of Ohio, have committed a tort in whole or in part in the State of Ohio, have substantial and continuing contact with the State of Ohio, and derive substantial revenue from goods used and consumed within the State of Ohio.

## FACTS

11. This is a product liability lawsuit related to Decedent's cardiac injuries, including suffering congestive heart failure and cardiomyopathy, caused by his consumption of Saxagliptin and Onglyza for the treatment of his Type 2 diabetes mellitus.

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

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.*

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

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

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[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/fda-panel-recommends-new-cv-safety-warnings-on-onglyza-and-nesina-dpp-4s/ (last viewed November 27, 2017).

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

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

**DECEDENT'S INJURIES**

25. Decedent, Charles Marcum, ingested Onglyza and/or Saxagliptin from approximately June 2012 to July 2016 as part of his diabetes treatment.

26. The Onglyza and/or Saxagliptin used by Decedent was manufactured, packaged, marketed, sold and/or distributed by Defendants, and it reached Decedent without substantial change in the drug's condition.

27. While using Onglyza and/or Saxagliptin, and as a direct and proximate result thereof, Decedent developed serious and permanent adverse effects including but not limited to congestive heart failure in October 2015.

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

29. At all relevant times, Defendants had knowledge that there was a significant increased risk of adverse events associated with Onglyza and/or 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 Onglyza and/or Saxagliptin.

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

31. Decedent's prescribing physicians would not have prescribed Onglyza and Saxagliptin to him, would have changed the way in which they treated Decedent's relevant conditions, changed the way they warned Decedent about the signs and symptoms of serious adverse effects of Onglyza and Saxagliptin, and discussed with Decedent 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 Onglyza and Saxagliptin.

32. Decedent'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 Onglyza and/or Saxagliptin, and, if they had been informed, would have used and prescribed alternative therapies to Decedent.

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

34. 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 Decedent, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

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

36. No limitations period should accrue until such time as Decedent knew or reasonably should have known of some causal connection between the use of Onglyza and 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 Plaintiffs knew or should have known the facts alleged herein.

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

38. 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.

## COUNT I
## STRICT PRODUCTS LIABILITY

39. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

40. Defendants were and are engaged in the business of manufacturing, marketing, distributing, promoting and selling Onglyza and Saxagliptin in the State of Ohio, including in the Southern District of Ohio.

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

42. Onglyza and Saxagliptin were expected to reach, and did reach, users and consumers, including Decedent, without substantial change in their defective and unreasonably dangerous condition.

43. Onglyza and Saxagliptin was used by Decedent in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

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

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

b. The drugs were not safe because the health risks associated with each product outweighed the benefits.

c. The drugs were marketed and promoted for use when they carried an unreasonable and unnecessary risk of serious injury.

d. The drugs were insufficiently and/or inadequately tested by Defendants.

e. The drugs were not safe due, in part, to inadequate and defective instructions and inadequate and defective warnings provided by Defendants.

f. The drugs were 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. The drugs were 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. The drugs were 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. The drugs were unsafe for normal or reasonably anticipated use. Said products were defective and unreasonably dangerous in design, construction and/or composition.

j. The drugs were defective and unreasonably dangerous because the products did not conform to an express warranty of the manufacturer about the product.

k. The drugs were 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.

45. The Onglyza and Saxagliptin 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.

46. A reasonable person who had actual knowledge of the increased risks associated with using the drugs would have concluded that Onglyza and Saxagliptin should not have been marketed to or used by Decedent and his physicians.

47. Despite the fact Defendants knew or should have known of the defective nature of the drugs, Defendants continued to design, manufacture and sell Onglyza and 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 Onglyza and Saxagliptin.

48. Decedent 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 Onglyza and Saxagliptin.

49. Decedent was not aware of the aforementioned defects at any time prior to the injuries caused by Onglyza and Saxagliptin.

50. Had adequate information regarding the safety of the products been provided to Decedent, he would not have used Onglyza and Saxagliptin.

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

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

53. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## COUNT II
## NEGLIGENCE

54. Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

56. At all relevant and material times, Defendants had a duty to Decedent to exercise reasonable care in the design, manufacture, advertising, marketing, labeling, packaging, distribution, post-market safety monitoring, reporting of adverse events, and sale of Onglyza and Saxagliptin, including a duty to ensure that the products did not cause users such as Decedent to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

57. Defendants breached their duty of care to Decedent 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 Onglyza and Saxagliptin which would have shown Onglyza and 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 Decedent;

b. Failing to design Onglyza and 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 Onglyza and Saxagliptin;

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

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

f. Designing, manufacturing, marketing, advertising, distributing, and selling Onglyza and Saxagliptin to consumers, including Decedent, 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 Onglyza and Saxagliptin;

h. Failing to use due care in the preparation, design and development of Onglyza and 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 Decedent, consumers, the medical community, and the FDA;

j. Failing to accompany Onglyza and 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 Onglyza and 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 Onglyza and 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 Decedent of the danger of adverse medical conditions from the use of Onglyza and Saxagliptin; and

q. Failing to label Onglyza and Saxagliptin to adequately warn Decedent of the serious adverse side effects with the use of the two drugs.

58. Defendants advertised, marketed, sold and distributed Onglyza and 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 Decedent and Decedent's healthcare providers would not have been aware.

59. 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.

60. 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.

61. 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 Decedent 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 Decedent's injuries.

62. 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 Decedent 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 Decedent's injuries.

63. Despite the fact Defendants knew or should have known that Onglyza and 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 Decedent.

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

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

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

67. 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 Decedent and any non-defendant physicians would rely upon such representations, leading to the use of Onglyza and Saxagliptin as described.

68. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Onglyza and 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 Onglyza and Saxagliptin.

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

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

71. Decedent and his 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 Onglyza and Saxagliptin to employ these products.

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

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

74. Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**COUNT III**
**FAILURE TO WARN**

75. Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

76. Onglyza and Saxagliptin were unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

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

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

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

80. Decedent was administered the Onglyza and Saxagliptin for their intended purpose.

81. Decedent used Onglyza and Saxagliptin in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

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

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

84. Decedent could not have discovered any defect in the Onglyza and Saxagliptin through the exercise of reasonable care.

85. Defendants, as manufacturers of Onglyza and 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 Onglyza and Saxagliptin was incomplete and inadequate.

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

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

88. Defendants marketed, promoted, distributed and sold unreasonably dangerous and defective prescription Onglyza and Saxagliptin to health care providers empowered to prescribe and dispense to consumers, including Decedent, 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 Onglyza and Saxagliptin, which resulted in injury to Decedent.

89. Defendants knew or should have known that Onglyza and Saxagliptin caused unreasonable and dangerous side effects and they continued to promote and market Onglyza and Saxagliptin without stating safer and more or equally effective alternative drug products existed and/or providing adequate clinically relevant information and data.

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

91. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including to Decedent and his 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 Decedent's physicians to the dangerous risks of Onglyza and 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 Decedent and his physicians that Onglyza and 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 Onglyza and Saxagliptin; and

d. Defendants continued to aggressively promote and sell Onglyza and 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 Onglyza and Saxagliptin.

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

93. Defendants had a duty and obligation to provide Decedent and his physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Onglyza and Saxagliptin, and/or that there existed safer and more or equally effective alternative drug products, but failed to do so.

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

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

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

97. Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**COUNT IV**
**OHIO PRODUCTS LIABILITY ACT**

98. Plaintiff incorporates each of the allegations above as if set forth fully herein.

99. Defendants are liable to Plaintiff and Decedent pursuant to the Ohio Products Liability Act (ORC Ann. 2307.71, *et seq*.).

100. Defendants were in the business of manufacturing, distributing, selling and marketing Onglyza and Saxagliptin. Defendants and/or their agents designed, formulated, manufactured, assembled, prepared for sale, distributed, and/or sold the drugs to Decedent in a defective condition unreasonably dangerous when applied to their intended use in the usual and customary manner.

101. Privity existed between Plaintiff/Decedent and Defendants.

102. Decedent Charles Marcum, while consuming Onglyza and Saxagliptin in the usual and customary manner they were intended to be used, suffered substantial injuries as a proximate result of Defendants placing the product on the market, which was unreasonably dangerous and defective at the time it was placed on the market by Defendants.

103. The Onglyza and Saxagliptin, at the time of the Decedent's consumption and injuries, was in substantially the same condition as it was at the time the Onglyza and Saxagliptin were marketed by Defendants.

104. As a direct and proximate result of Defendants' conduct, Decedent was injured and is entitled to recover damages for her bodily injuries, physical and mental pain, past and future medical expenses, past and future pain and suffering, and permanent injury.

105. Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

**REQUEST FOR PUNITIVE DAMAGES**

106. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

107. At all times relevant herein, Defendants knew that Onglyza and Saxagliptin were dangerous and defective; concealed the dangers and risks from Decedent, and the public at large; made misrepresentations to Decedent, and the public in general as previously stated herein as to the safety and efficacy of the drugs; and with full knowledge of the risks associated with the drugs and without adequate warnings of the same, manufactured, designed, packaged, labeled, marketed, advertised, distributed and sold Onglyza and Saxagliptin to the general public and to Decedent.

108. Defendants engaged in malicious, fraudulent and oppressive conduct toward Decedent and the public, acted with willful and wanton and/or conscious and/or reckless disregard for the safety of Plaintiff and the general public.

109. Defendants consciously and deliberately engaged in wanton disregard of the rights and safety of the Decedent.

110. Defendants had actual knowledge of the defective nature of Onglyza and Saxagliptin and their capacity to cause injury.

111. Decedent's injuries are a result of fraud, malice, and/or gross negligence on the part of the Defendants.

112. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff is entitled to a recovery of punitive damages.

**WHEREFORE,** Plaintiff demands judgment against the Defendants and requests:

a) A trial by jury;

b) Judgment against Defendants for all compensatory and punitive damages allowable to Plaintiff;

c) Judgment against Defendants for all other relief sought by Plaintiff under this Complaint;

d) An order for all costs and attorneys' fees; and

e) Such further relief which the Court deems just and appropriate.

Dated: April 27, 2018

Respectfully submitted,

**PEIFFER ROSCA WOLF ABDULLAH CARR & KANE**
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*Attorneys for Plaintiff*

JS 44 (Rev. 06/17)

# 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

PHYLLIS MARCUM, ON BEHALF OF THE ESTATE OF CHARLES MARCUM

**(b)** County of Residence of First Listed Plaintiff Fairfield, OH
*(EXCEPT IN U.S. PLAINTIFF CASES)*

**(c)** Attorneys *(Firm Name, Address, and Telephone Number)*
James P. Booker
1422 Euclid Avenue, Suite 1610
Cleveland, OH 44115; T: (216) 589-9280

## DEFENDANTS

Bristol-Myers Squibb, Astrazeneca Pharmaceuticals, LP

County of Residence of First Listed Defendant New Castle, DE
*(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
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 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)*

Click here for: Nature of Suit Code Descriptions.

**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

**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

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

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

**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

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

**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

**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

**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

## 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 - Transfer ☐ 8 Multidistrict Litigation - Direct File

## 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

Brief description of cause:
Heart failure product liability claim due to Onglyza (saxagliptin) pharmaceutical.

## 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 _____ DOCKET NUMBER _____

DATE
04/27/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/James P. Booker

**FOR OFFICE USE ONLY**

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

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# 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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

**V.** **Origin.** Place an "X" in one of the seven 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 – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

**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.