

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
LEXINGTON DIVISION**

DAVID TAYLOR, and)	
)	
LEATHA TAYLOR)	
)	
Plaintiffs)	
)	
v.)	Case No.:
)	
BRISTOL-MYERS SQUIBB CO., Inc.;)	
)	
ASTRAZENECA PHARMACEUTICALS)	
LP;)	
)	
IPR PHARMACEUTICALS, Inc., and)	
)	
MCKESSON CORP.)	
)	
Defendants.)	
_____)	

COMPLAINT

Plaintiffs David Taylor and Leatha Taylor (“Plaintiffs”), tender the following Complaint and Jury Demand against Defendants for personal injuries suffered from the consumption of Saxagliptin pharmaceutical products, sold under the brand name Onglyza.

PARTIES

1. At all times relevant to this Complaint, Plaintiffs have been and continues to be a resident and citizen of Cherry Lane in Clay City, Kentucky, which is located in Powell County, Kentucky.

2. 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 Eastern

District of Kentucky including manufacturing, labeling, packaging, marketing, advertising, distributing and selling Saxagliptin.

3. Defendant AstraZeneca Pharmaceuticals LP (“AZ”) is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, DE 19850. At all relevant times, AZ regularly and continuously did business within the Eastern District of Kentucky including manufacturing, labeling, packaging, marketing, advertising, distributing and selling Saxagliptin.

4. Defendant IPR Pharmaceuticals, Inc. (“IPR”) is a Puerto Rico corporation with its principal place of business at Road 188, Lot 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729. At all relevant times, IPR regularly and continuously did business within the Eastern District of Kentucky including manufacturing, labeling, packaging, marketing, advertising, distributing and selling Saxagliptin.

5. 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 regularly and continuously did business within the Eastern District of Kentucky 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 Kentucky.

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 Plaintiffs 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 Plaintiffs reside.

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 Plaintiffs' claims occurred, in part, in this District, and because Defendants conduct substantial business in this District. Powell County, where Plaintiffs reside, is furthermore part of the Eastern District of the United States District Court for Kentucky, in the Lexington Division.

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

FACTS

11. This is a product liability lawsuit related to Plaintiff's cardiac injuries, including suffering myocardial infarction, 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 Commonwealth of Kentucky to fraudulently convey false and misleading information concerning the safety and efficacy of Saxagliptin and Onglyza 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 and Onglyza

from the public, including Plaintiff David Taylor, his 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.

13. Plaintiff Leatha Taylor brings a claim for loss of consortium due to her husband's personal injuries.

14. 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.

15. 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.

16. 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.

17. 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

¹ *Id.*

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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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. At no time did Defendants perform adequate safety testing on

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

Saxagliptin prior to marketing their drugs to the American public and failed to do so until performing the SAVOR trial.

25. 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.

PLAINTIFF'S INJURIES

26. Plaintiff, David Taylor, ingested Onglyza and/or Saxagliptin from approximately April 2015 to June 2015 as part of his diabetes treatment.

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

28. While using Onglyza and/or Saxagliptin, and as a direct and proximate result thereof, Plaintiff developed serious and permanent adverse effects including but not limited to suffering myocardial infarction in July 2015.

29. 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.

30. 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.

31. 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 Onglyza and Saxagliptin including but not limited to heart failure, congestive heart failure, cardiac failure, and death related to those events.

32. Plaintiff's prescribing physicians would not have prescribed Onglyza and Saxagliptin to him, 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 Onglyza and 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 Onglyza and Saxagliptin.

33. 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 Onglyza and/or Saxagliptin, and, if they had been informed, would have used and prescribed alternative therapies to Plaintiff.

34. 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, diminishment of earning potential, and other pecuniary losses.

35. 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.

36. As a result of Defendants' actions, Plaintiff David Taylor and his 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.

37. No limitations period should accrue until such time as Plaintiffs 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, Plaintiffs hereby invoke 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.

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

39. 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

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

41. Defendants were and are engaged in the business of manufacturing, marketing, distributing, promoting and selling Onglyza and Saxagliptin in the Commonwealth of Kentucky, including in the Eastern District of Kentucky, U.S. District Court.

42. 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.

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

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

45. 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 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. 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.

46. 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.

47. 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 Plaintiff and his physicians.

48. 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. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by Onglyza and Saxagliptin.

49. 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 Onglyza and Saxagliptin.

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

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

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

53. 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.

54. WHEREFORE, Plaintiffs demand 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

55. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

57. 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 Onglyza and 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.

58. 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 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 Plaintiff;

- 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 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 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 Plaintiff, 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 Plaintiff 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 Plaintiff of the serious adverse side effects with the use of the two drugs.

59. 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 Plaintiff and Plaintiff's healthcare providers would not have been aware.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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 Plaintiff.

65. Defendants negligently and recklessly represented to Plaintiffs, 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.

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

67. 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.

68. 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 Onglyza and Saxagliptin as described.

69. 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.

70. 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 Plaintiff, as well as the medical community, the FDA and the consuming public.

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

72. Plaintiff 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.

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

74. Had Plaintiff 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, Plaintiff would not have used these products.

75. Plaintiffs demand 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

76. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

78. 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 Plaintiff.

79. 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.

80. The Onglyza and Saxagliptin manufactured by Defendants reached Plaintiff 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 Plaintiff.

81. Plaintiff was administered the Onglyza and Saxagliptin for their intended purpose.

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

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

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

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

86. 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.

87. 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 her treating physicians. The warnings given by Defendants were inaccurate, unclear, ambiguous, and/or incomplete.

88. Defendants had a continuing duty to provide consumers, including Plaintiff, 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.

89. 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 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 Onglyza and Saxagliptin, which resulted in injury to Plaintiff.

90. 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.

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

92. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including to Plaintiff 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 Plaintiff'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 Plaintiff and his physicians that Onglyza and 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 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.

93. 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.

94. Defendants had a duty and obligation to provide Plaintiff 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.

95. By failing to provide Plaintiff 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.

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

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

98. Plaintiffs demand 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
BREACH OF WARRANTY OF MERCHANTABILITY

99. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

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

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

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

104. The Onglyza and Saxagliptin used by Plaintiff were not safe, of merchantable quality, or fit for their intended use.

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

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

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

108. Plaintiffs demand 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 V
BREACH OF EXPRESS WARRANTY

109. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

111. Defendants expressly represented to Plaintiff, consumers and the medical community that Onglyza and Saxagliptin were safe, efficacious, fit for use in persons with Type 2 diabetes mellitus, of merchantable quality, adequately tested, well tolerated in adequate and well-controlled clinical studies, and did not increase the risk of experiencing serious, life threatening side effects.

112. Defendants breached those express warranties as follows:

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

b. Defendants misrepresented the risks associated with using Onglyza and 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 Onglyza and Saxagliptin were as safe or safer than other available forms of treatment for Plaintiff's conditions;

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

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

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

115. At all relevant times, Onglyza and Saxagliptin did not perform in accordance with the Defendants' representations because Onglyza and Saxagliptin are not safe and cause high levels of serious side effects.

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

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

118. Plaintiffs demand individual 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 VI
BREACH OF IMPLIED WARRANTY

119. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

121. Defendants impliedly warranted to Plaintiff that Onglyza and Saxagliptin were safe for use by Plaintiff and the consuming population.

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

123. Plaintiff and his healthcare providers used Onglyza and Saxagliptin as intended and directed by the Defendants, and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

124. Plaintiff was a foreseeable user of Defendants' product, Onglyza and Saxagliptin. They were 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.

125. Plaintiff and his healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants, and upon the Defendants' implied warranty that Onglyza and Saxagliptin were safe, of merchantable quality, and fit for use.

126. The Onglyza and Saxagliptin used by Plaintiff were not safe, of merchantable quality, nor fit for use.

127. The Onglyza and Saxagliptin used by Plaintiff did not perform in accordance with Defendants' representations because Onglyza and Saxagliptin are not safe and cause high levels of serious, life-threatening side effects including the injuries Plaintiff experienced.

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

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

COUNT VII
KENTUCKY CONSUMER PROTECTION ACT

130. Plaintiffs incorporate each of the allegations above as if set forth fully herein.

131. Defendants are liable to Plaintiff pursuant to the Kentucky Consumer Protection Act (hereinafter "KCPA").

132. 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 Plaintiff in a defective condition unreasonably dangerous when applied to their intended use in the

usual and customary manner.

133. Privity existed between Plaintiff and Defendants.

134. Plaintiff David Taylor, 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.

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

136. As a direct and proximate result of Defendants' conduct, Plaintiff 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.

137. 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.

COUNT VIII
LOSS OF CONSORTIUM

138. Plaintiffs David Taylor and Leatha Taylor incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

139. Because of Defendants' conduct as described above, and the corresponding injuries sustained by Plaintiff's spouse, Plaintiff Leatha Taylor is entitled to recover for the

loss of services, assistance, aid, society, companionship, and conjugal relationship between she and her husband David Taylor.

REQUEST FOR PUNITIVE DAMAGES

140. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

141. At all times relevant herein, Defendants knew that Onglyza and Saxagliptin were dangerous and defective; concealed the dangers and risks from Plaintiff, and the public at large; made misrepresentations to Plaintiff, 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 Plaintiff.

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

143. Defendants consciously and deliberately engaged in wanton disregard of the rights and safety of the Plaintiff.

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

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

146. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiffs are entitled to a recovery of punitive damages.

WHEREFORE, Plaintiffs 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.

Respectfully submitted,

JONES WARD PLC

/s/ Alex C. Davis _____

Jasper D. Ward IV

Alex C. Davis

312 S. Fourth Street, 6th Floor

Louisville, Kentucky 40202

T: (502) 882-6000

F: (502) 587-2007

jasper@jonesward.com

alex@jonesward.com

Counsel for Plaintiff

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Civil Action No. _____

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Server's address

Additional information regarding attempted service, etc:

JS 44 (Rev. 07/16)

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.)

<p>I. (a) PLAINTIFFS David Taylor, Leatha Taylor</p> <p>(b) County of Residence of First Listed Plaintiff <u>Powell</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p>(c) Attorneys <i>(Firm Name, Address, and Telephone Number)</i> Alex C. Davis, Jasper D. Ward IV Jones Ward PLC, 312 S. Fourth Street, Sixth Floor Louisville, Kentucky 40202</p>	<p>DEFENDANTS Bristol-Meyers Squibb Co., Inc; Astrazeneca Pharmaceuticals LP; IPR Pharmaceuticals, Inc.; McKesson Corp.</p> <p>County of Residence of First Listed Defendant <u>New Castle (Delaware)</u> <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys <i>(If Known)</i></p>
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<p>II. BASIS OF JURISDICTION <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input checked="" type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <p><i>(For Diversity Cases Only)</i></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;"></td> <td style="width:33%; text-align: center;">PTF</td> <td style="width:33%; text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> </tr> <tr> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5																				
Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

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

<p>CONTRACT</p> <p><input type="checkbox"/> 110 Insurance</p> <p><input type="checkbox"/> 120 Marine</p> <p><input type="checkbox"/> 130 Miller Act</p> <p><input type="checkbox"/> 140 Negotiable Instrument</p> <p><input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment</p> <p><input type="checkbox"/> 151 Medicare Act</p> <p><input type="checkbox"/> 152 Recovery of Defaulted Student Loans <i>(Excludes Veterans)</i></p> <p><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits</p> <p><input type="checkbox"/> 160 Stockholders' Suits</p> <p><input type="checkbox"/> 190 Other Contract</p> <p><input type="checkbox"/> 195 Contract Product Liability</p> <p><input type="checkbox"/> 196 Franchise</p>	<p>TORTS</p> <p>PERSONAL INJURY</p> <p><input type="checkbox"/> 310 Airplane</p> <p><input type="checkbox"/> 315 Airplane Product Liability</p> <p><input type="checkbox"/> 320 Assault, Libel & Slander</p> <p><input type="checkbox"/> 330 Federal Employers' Liability</p> <p><input type="checkbox"/> 340 Marine</p> <p><input type="checkbox"/> 345 Marine Product Liability</p> <p><input type="checkbox"/> 350 Motor Vehicle</p> <p><input type="checkbox"/> 355 Motor Vehicle Product Liability</p> <p><input type="checkbox"/> 360 Other Personal Injury</p> <p><input type="checkbox"/> 362 Personal Injury - Medical Malpractice</p> <p>PERSONAL INJURY</p> <p><input type="checkbox"/> 365 Personal Injury - Product Liability</p> <p><input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability</p> <p><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability</p> <p>PERSONAL PROPERTY</p> <p><input type="checkbox"/> 370 Other Fraud</p> <p><input type="checkbox"/> 371 Truth in Lending</p> <p><input type="checkbox"/> 380 Other Personal Property Damage</p> <p><input type="checkbox"/> 385 Property Damage Product Liability</p>	<p>FORFEITURE/PENALTY</p> <p><input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881</p> <p><input type="checkbox"/> 690 Other</p> <p>LABOR</p> <p><input type="checkbox"/> 710 Fair Labor Standards Act</p> <p><input type="checkbox"/> 720 Labor/Management Relations</p> <p><input type="checkbox"/> 740 Railway Labor Act</p> <p><input type="checkbox"/> 751 Family and Medical Leave Act</p> <p><input type="checkbox"/> 790 Other Labor Litigation</p> <p><input type="checkbox"/> 791 Employee Retirement Income Security Act</p> <p>IMMIGRATION</p> <p><input type="checkbox"/> 462 Naturalization Application</p> <p><input type="checkbox"/> 465 Other Immigration Actions</p>	<p>BANKRUPTCY</p> <p><input type="checkbox"/> 422 Appeal 28 USC 158</p> <p><input type="checkbox"/> 423 Withdrawal 28 USC 157</p> <p>PROPERTY RIGHTS</p> <p><input type="checkbox"/> 820 Copyrights</p> <p><input type="checkbox"/> 830 Patent</p> <p><input type="checkbox"/> 840 Trademark</p> <p>SOCIAL SECURITY</p> <p><input type="checkbox"/> 861 HIA (1395ff)</p> <p><input type="checkbox"/> 862 Black Lung (923)</p> <p><input type="checkbox"/> 863 DIWC/DIWW (405(g))</p> <p><input type="checkbox"/> 864 SSID Title XVI</p> <p><input type="checkbox"/> 865 RSI (405(g))</p> <p>FEDERAL TAX SUITS</p> <p><input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)</p> <p><input type="checkbox"/> 871 IRS—Third Party 26 USC 7609</p>	<p>OTHER STATUTES</p> <p><input type="checkbox"/> 375 False Claims Act</p> <p><input type="checkbox"/> 376 Qui Tam (31 USC 3729(a))</p> <p><input type="checkbox"/> 400 State Reapportionment</p> <p><input type="checkbox"/> 410 Antitrust</p> <p><input type="checkbox"/> 430 Banks and Banking</p> <p><input type="checkbox"/> 450 Commerce</p> <p><input type="checkbox"/> 460 Deportation</p> <p><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations</p> <p><input type="checkbox"/> 480 Consumer Credit</p> <p><input type="checkbox"/> 490 Cable/Sat TV</p> <p><input type="checkbox"/> 850 Securities/Commodities/Exchange</p> <p><input type="checkbox"/> 890 Other Statutory Actions</p> <p><input type="checkbox"/> 891 Agricultural Acts</p> <p><input type="checkbox"/> 893 Environmental Matters</p> <p><input type="checkbox"/> 895 Freedom of Information Act</p> <p><input type="checkbox"/> 896 Arbitration</p> <p><input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision</p> <p><input type="checkbox"/> 950 Constitutionality of State Statutes</p>
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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:
Plaintiff suffered cardiac injuries as a result of the use of 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 _____ DOCKET NUMBER _____

DATE: 07/13/2016 SIGNATURE OF ATTORNEY OF RECORD: /s/ Alex C. Davis

FOR OFFICE USE ONLY

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