

**IN THE UNITED STATES DISTRICT  
NORTHERN DISTRICT OF GEORGIA  
NEWNAN DIVISION**

WILEY WILLIAMS, JR. and )  
RHUDENIA WILLIAMS, )

Plaintiffs, )

vs. )

CIVIL ACTION  
FILE NO.

3:18-CV-82-TCB

BRISTOL-MEYERS SQUIBB CO., )

INC., ASTRAZENECA )

PHARMACEUTICALS LP, IPR )

PHARMACEUTICALS, INC., )

MCKESSON CORPORATION, ET )

AL., )

Defendants. )

**JURY TRIAL DEMANDED**

**COMPLAINT**

Plaintiffs Wiley Williams Jr. and Rhudenia Williams hereby file this Complaint and Jury Demand against Defendants for personal injuries suffered from Wiley Williams Jr.’s consumption of Saxagliptin pharmaceutical products, sold under the brand name Onglyza.

**PARTIES**

1. At all times relevant to this Complaint, Plaintiffs have been and continue to be a residents and citizens of Fayetteville, Georgia, which is located in Fayette County, Georgia.

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

3. 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 Northern District of Georgia 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 Northern District of Georgia 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 Northern District of Georgia 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 Georgia.

**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. Fayette County, where Plaintiffs reside, is furthermore part of the Norther District of the United States District Court for Georgia.

10. This Court has personal jurisdiction over the Defendants because

they have done business in the Georgia, have committed a tort in whole or in part in the Georgia, have substantial and continuing contact with the Georgia, and derive substantial revenue from goods used and consumed within the Georgia.

### **FACTS**

11. This is a product liability lawsuit related to Plaintiff's cardiac injuries, including suffering Congestive Heart Failure, 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 Georgia to fraudulently convey false and misleading information concerning the safety 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 Plaintiff Wiley Williams, 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 Rhudenia S. Williams 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.

17. 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.

18. In December 2008, with knowledge of the increased cardiovascular

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



19. 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.

20. 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.

21. 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.

22. 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.<sup>1</sup> 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.

23. In addition to Defendants refusing and failing to warn of the risks of heart failure, congestive heart failure, cardiac failure and death, Defendants'

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<sup>1</sup> 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 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.

24. 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.

25. 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

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

27. 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**

28. Plaintiff, Wiley Williams, ingested Onglyza and/or Saxagliptin from approximately November 2012 to May 2013 as part of his diabetes treatment.

29. 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.

30. 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 Congestive Heart Failure on June 4, 2013.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

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

41. 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**

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

43. Defendants were and are engaged in the business of manufacturing, marketing, distributing, promoting and selling Onglyza and Saxagliptin in Georgia, including in the Northern District of Georgia, U.S. District Court.

44. 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.

45. 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.

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

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

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

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

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

55. 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.

56. 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**

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

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

59. 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.

60. 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 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

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

74. 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.

75. 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.

76. 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.

77. 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**

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

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

80. 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.

81. 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.

82. 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.

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

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

85. 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.

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

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

88. 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.

89. 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.



90. 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.

91. 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.

92. 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.

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

94. 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 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.

95. 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.

96. 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.

97. 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.

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

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

100. 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**

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

102. 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.

103. 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.

104. 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.

105. 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.

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

107. 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.

108. 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.

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

110. 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**

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

112. 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.

113. 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.

114. 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.

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

116. 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.

117. 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.

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

119. 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.

120. 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**

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

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

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

124. 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.

125. 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.

126. 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.

127. 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.

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

129. 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.

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

131. 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**  
**LOSS OF CONSORTIUM**

132. Plaintiffs Wiley Williams Jr. and Rhudenia S. Williams incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

133. Because of Defendants' conduct as described above, and the corresponding injuries sustained by Plaintiff's spouse, Plaintiff Rhudenia S. Williams is entitled to recover for the loss of services, assistance, aid, society, companionship, and conjugal relationship between she and her husband Wiley Williams Jr..

### **REQUEST FOR PUNITIVE DAMAGES**

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

135. 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.

136. 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.

137. Defendants consciously and deliberately engaged in wanton

disregard of the rights and safety of the Plaintiff.

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

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

140. 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 demand judgment against the Defendants and requests:

- a) A trial by jury;
- b) Judgment against Defendants for all compensatory and punitive damages allowable to Plaintiffs;
- c) Judgment against Defendants for all other relief sought by Plaintiffs 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,

/s/Dylan J. Hooper

Dylan J. Hooper  
Georgia Bar No.: 194606  
*Attorney for Plaintiff*

Morgan & Morgan Atlanta, PLLC.  
191 Peachtree Street, NE, Suite 4200  
P.O. Box 57007  
Atlanta, Georgia 30343-1007  
Telephone: (404) 965-8811

/s/ Frank Petosa

Frank M. Petosa  
FL Bar No. 972754  
*Attorney for Plaintiff*  
*Pro Hac Vice pending*

Morgan & Morgan  
Complex Litigation Group  
600 N. Pine Island Road  
Suite 400  
Plantation, FL 33324  
Telephone: (954) 318-0268  
Facsimile: (954) 327-3018

/s/ Henry Watkins  
Henry Watkins  
FL Bar No. 115845  
*Attorney for Plaintiff*  
*Pro Hac Vice pending*

Morgan & Morgan  
Complex Litigation Group  
600 N. Pine Island Road  
Suite 400  
Plantation, FL 33324  
Telephone: (954) 318-0268  
Facsimile: (954) 327-3018



**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that copies of the foregoing will be electronically uploaded via the CM/ECF System, which will provide electronic service and notification to all counsel of record who are registered as CM/ECF users.

This 25<sup>th</sup> day of July 2018,

/s/Dylan J. Hooper

Dylan J. Hooper

Georgia Bar No.: 194606

Attorney for Plaintiff

Morgan & Morgan Atlanta, PLLC.  
191 Peachtree Street, NE, Suite 4200  
P.O. Box 57007  
Atlanta, Georgia 30343-1007  
Telephone: (404) 965-8811

/s/ Frank M. Petosa

Frank M. Petosa

FL Bar No. 972754

*Attorney for Plaintiff*

*Pro Hac Vice pending*

Morgan & Morgan  
Complex Litigation Group  
600 N. Pine Island Road  
Suite 400  
Plantation, FL 33324  
Telephone: (954) 318-0268  
Facsimile: (954) 327-3018

**RULE 5.1B CERTIFICATE OF TYPE, FORMAT, AND FONT SIZE**

Pursuant to Local Rule 5.1B of the United States District Court of the Northern District of Georgia, the undersigned certifies that the foregoing submission to the Court was computer processed, double spaced between lines, and used Times New Roman font of 14 point size.

This 25<sup>th</sup> day of July 2018,

/s/Dylan J. Hooper

Dylan J. Hooper

Georgia Bar No.: 194606

*Attorney for Plaintiff*

Morgan & Morgan Atlanta, PLLC.  
191 Peachtree Street, NE, Suite 4200  
P.O. Box 57007  
Atlanta, Georgia 30343-1007  
Telephone: (404) 965-8811

/s/ Frank M. Petosa

Frank M. Petosa

FL Bar No. 972754

*Attorney for Plaintiff*

*Pro Hac Vice pending*

Morgan & Morgan  
Complex Litigation Group  
600 N. Pine Island Road  
Suite 400  
Plantation, FL 33324  
Telephone: (954) 318-0268  
Facsimile: (954) 327-3018

JS44 (Rev. 6/2017 NDGA)

**CIVIL COVER SHEET**

The JS44 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 is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

**I. (a) PLAINTIFF(S)**  
 WILEY WILLIAMS, JR. and RHUDENIA WILLIAMS

**DEFENDANT(S)**  
 BRISTOL-MEYERS SQUIBB CO., INC., ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., MCKESSON CORPORATION, ET AL.,

**(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF**  
 \_\_\_\_\_  
 (EXCEPT IN U.S. PLAINTIFF CASES)

**COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT**  
 \_\_\_\_\_  
 (IN U.S. PLAINTIFF CASES ONLY)

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

**(c) ATTORNEYS** (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)

Morgan & Morgan  
 Complex Litigation Group  
 600 N. Pine Island Road  
 Suite 400  
 Plantation, FL 33324

**ATTORNEYS** (IF KNOWN)

**II. BASIS OF JURISDICTION**  
 (PLACE AN "X" IN ONE BOX ONLY)

**III. CITIZENSHIP OF PRINCIPAL PARTIES**  
 (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)  
 (FOR DIVERSITY CASES 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)

- |                                       |                            |                            |                                       |  |
|---------------------------------------|----------------------------|----------------------------|---------------------------------------|--|
| PLF                                   | DEF                        | PLF                        | DEF                                   |  |
| <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            | CITIZEN OF THIS STATE INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE        |
| <input type="checkbox"/> 2            | <input type="checkbox"/> 2 | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 | CITIZEN OF ANOTHER STATE INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE |
| <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            | CITIZEN OR SUBJECT OF A FOREIGN COUNTRY FOREIGN NATION                                 |

**IV. 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 District)
- 6 MULTIDISTRICT LITIGATION - TRANSFER
- 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT
- 8 MULTIDISTRICT LITIGATION - DIRECT FILE

**V. CAUSE OF ACTION** (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

Complete diversity of citizenship exists between Plaintiffs and Defendants. 28 U.S.C. § 1332.

(IF COMPLEX, CHECK REASON BELOW)

- 1. Unusually large number of parties.
- 2. Unusually large number of claims or defenses.
- 3. Factual issues are exceptionally complex.
- 4. Greater than normal volume of evidence.
- 5. Extended discovery period is needed.
- 6. Problems locating or preserving evidence.
- 7. Pending parallel investigations or actions by government.
- 8. Multiple use of experts.
- 9. Need for discovery outside United States boundaries.
- 10. Existence of highly technical issues and proof.

**CONTINUED ON REVERSE**

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \$ \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ MAG. JUDGE (IFP) \_\_\_\_\_  
 JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_ NATURE OF SUIT \_\_\_\_\_ CAUSE OF ACTION \_\_\_\_\_  
 (Referral)

**VI. NATURE OF SUIT** (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK

- 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK

- 110 INSURANCE
- 120 MARINE
- 130 MILLER ACT
- 140 NEGOTIABLE INSTRUMENT
- 151 MEDICARE ACT
- 160 STOCKHOLDERS' SUITS
- 190 OTHER CONTRACT
- 195 CONTRACT PRODUCT LIABILITY
- 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK

- 210 LAND CONDEMNATION
- 220 FORECLOSURE
- 230 RENT LEASE & EJECTMENT
- 240 TORTS TO LAND
- 245 TORT PRODUCT LIABILITY
- 290 ALL OTHER REAL PROPERTY

TORTS - PERSONAL INJURY - "4" MONTHS DISCOVERY TRACK

- 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
- 365 PERSONAL INJURY - PRODUCT LIABILITY
- 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK

- 370 OTHER FRAUD
- 371 TRUTH IN LENDING
- 380 OTHER PERSONAL PROPERTY DAMAGE
- 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK

- 422 APPEAL 28 USC 158
- 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK

- 440 OTHER CIVIL RIGHTS
- 441 VOTING
- 442 EMPLOYMENT
- 443 HOUSING/ ACCOMMODATIONS
- 445 AMERICANS with DISABILITIES - Employment
- 446 AMERICANS with DISABILITIES - Other
- 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK

- 462 NATURALIZATION APPLICATION
- 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK

- 463 HABEAS CORPUS- Alien Detainee
- 510 MOTIONS TO VACATE SENTENCE
- 530 HABEAS CORPUS
- 535 HABEAS CORPUS DEATH PENALTY
- 540 MANDAMUS & OTHER
- 550 CIVIL RIGHTS - Filed Pro se
- 555 PRISON CONDITION(S) - Filed Pro se
- 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK

- 550 CIVIL RIGHTS - Filed by Counsel
- 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK

- 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK

- 710 FAIR LABOR STANDARDS ACT
- 720 LABOR/MGMT. RELATIONS
- 740 RAILWAY LABOR ACT
- 751 FAMILY and MEDICAL LEAVE ACT
- 790 OTHER LABOR LITIGATION
- 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK

- 820 COPYRIGHTS
- 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK

- 830 PATENT
- 835 PATENT-ABBREVIATED NEW DRUG APPLICATIONS (ANDA) - a/k/a Hatch-Waxman cases

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK

- 861 HIA (1395f)
- 862 BLACK LUNG (923)
- 863 DIWC (405(g))
- 863 DIWW (405(g))
- 864 SSID TITLE XVI
- 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK

- 870 TAXES (U.S. Plaintiff or Defendant)
- 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK

- 375 FALSE CLAIMS ACT
- 376 Qui Tam 31 USC 3729(a)
- 400 STATE REAPPORTIONMENT
- 430 BANKS AND BANKING
- 450 COMMERCE/ICC RATES/ETC.
- 460 DEPORTATION
- 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- 480 CONSUMER CREDIT
- 490 CABLE/SATELLITE TV
- 890 OTHER STATUTORY ACTIONS
- 891 AGRICULTURAL ACTS
- 893 ENVIRONMENTAL MATTERS
- 895 FREEDOM OF INFORMATION ACT
- 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION
- 950 CONSTITUTIONALITY OF STATE STATUTES

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK

- 410 ANTI TRUST
- 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK

- 896 ARBITRATION (Confirm / Vacate / Order / Modify)

**\* PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

**VII. REQUESTED IN COMPLAINT:**

CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23 DEMAND \$ \_\_\_\_\_

JURY DEMAND  YES  NO (CHECK YES ONLY IF DEMANDED IN COMPLAINT)

**VIII. RELATED/REFILED CASE(S) IF ANY**

JUDGE \_\_\_\_\_ DOCKET NO. \_\_\_\_\_ MDL 2809

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)

- 1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.
- 4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.
- 5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.
- 6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):

7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO. \_\_\_\_\_, WHICH WAS DISMISSED. This case  IS  IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.

  
SIGNATURE OF ATTORNEY OF RECORD

7/25/18  
DATE