UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DIXIE WALKER and CHARLES WALKER, Plaintiff, -against- BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC., Defendants.	**Civil Action No. 2:16-cv-15940** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT AND JURY TRIAL DEMANDED

Plaintiffs, DIXIE WALKER and CHARLES WALKER, by and through their attorneys, Salim-Beasley, LLC and Napoli Shkolnik, PLLC, brings their complaint against Defendants BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC. (collectively, "Defendants"), as follows:

SUMMARY OF THE CASE

1. The action is brought by Plaintiffs DIXIE WALKER and CHARLES WALKER. On or about February 16, 2015, Plaintiff DIXIE WALKER was prescribed Eliquis, also known as apixaban, after fracturing her hip.

2. Plaintiff, CHARLES WALKER, at all times relevant hereto, was and is the spouse of DIXIE WALKER.

3. Defendants, BRISTOL-MYERS SQUIBB and PFIZER, INC., (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Eliquis, as well as dealt with governmental regulatory bodies.

4. In written information about the safety and risks of Eliquis, Defendants negligently and fraudulently represented to the medical and healthcare community, including Plaintiff's prescribing doctor, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Eliquis had been tested and was found to be safe and effective for its indicated uses.

5. Defendants concealed their knowledge of Eliquis' defects from Plaintiff, the FDA, and the public in general, and the medical community, including Plaintiff's prescribing physicians.

6. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community including Plaintiff's prescribing doctor, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and purchase Eliquis, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein. Plaintiffs and the prescribing physicians were not aware of the falsity of these representations.

7. As a result of the foregoing acts and omissions, the plaintiff, DIXIE WALKER, was caused to suffer serious and dangerous side effects including bleeding, physical pain and mental anguish, including diminished enjoyment of life.

PLAINTIFF

8. Upon information and belief, Plaintiff, DIXIE WALKER, ingested Eliquis from upon direction of her physician to reduce the risk of blood clots due to a fractured hip.

9. On or about February 22, 2015, as a direct and proximate result of Defendants' conduct, Plaintiff, DIXIE WALKER, experienced internal bleeding and severe pain and suffering.

10. Plaintiff was unaware that this bleeding was caused by Eliquis until February 2016.

11. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and incurred damages, including medical expenses, physical pain and mental anguish, diminished enjoyment of life, and loss of earnings, among other damages.

PARTY DEFENDANTS

12. Upon information and belief, at all times hereinafter mentioned, defendant, BRISTOL-MYERS SQUIBB COMPANY ("BMS"), was and is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 345 Park Avenue, New York, New York 10154. Its registered agent for service of process is: c/o CT Corporation System, 111 8th Avenue, New York, NY 10011. Defendant BMS is the holder of the approved New Drug Application ("NDA") for Eliquis as well as the supplemental NDA.

13. Defendant BMS is the holder of the approved New Drug Application ("NDA") for Eliquis as well as the supplemental NDA.

14. As part of its business, BMS was and is involved in the research, development, sales, and marketing of pharmaceutical products including Eliquis.

15. At all relevant times, Defendant BMS was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Eliquis for use as an oral anticoagulant.

16. Upon information and belief, at all times hereinafter mentioned, defendant, PFIZER INC. ("Pfizer"), was and is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New York 10017. Its registered agent for service of process is: c/o CT Corporation System, 111 8th Avenue, New York, NY 10011.

17. Defendant PFIZER was and is in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Eliquis for use as an oral anticoagulant.

18. In 2007, Defendants entered into a worldwide collaboration to "commercialize" apixaban (Eliquis), which they have promoted as combining BMS's "long-standing strengths in cardiovascular drug development and commercialization" with Pfizer's "global scale and expertise in their field."

JURISDICTION AND VENUE

19. Plaintiffs are residents and citizens of the State of Louisiana, Saint Tammany Parish.

20. Jurisdiction is proper in federal court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiff and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

FACTUAL ALLEGATIONS

21. Atrial fibrillation is a common arrhythmia (abnormal heart beat) that increases the risk of blood clot formation, which gives rise to the potential for embolism and increased risk for stroke.

22. For generations, warfarin (Coumadin) has been prescribed for its anticoagulation effect by inhibiting certain clotting factors within the coagulation cascade. Warfarin works by blocking clotting factors that rely on Vitamin K. Vitamin K is used by multiple clotting factors to help the blood clot.

23. All anticoagulants have a risk of bleeding. Without an antidote, a bleed can

quickly become a life-threatening situation. If a patient presents to the emergency room with a bleed on warfarin, doctors have a variety of options to choose from depending on how quickly they need to reverse anticoagulation. Because warfarin is a vitamin K antagonist, a patient on warfarin presenting with bleeding can have the anticoagulation effects completely reversed within a very short amount of time by administering vitamin K.

24. Although warfarin is quickly reversible in the event of a bleed, one drawback is the amount of monitoring. Patients taking warfarin must be monitored every few weeks. Doctors test the amount of time it takes for a patient's blood to clot using the prothrombin time test. The prothrombin test measures the International Normalized Ration (INR). A high INR indicates a high risk of uncontrollable bleeding; a low INR indicates a high risk for blood clots. In addition, patients taking warfarin must follow a strict diet since many green, leafy vegetable contain high amounts of Vitamin K.

25. Given the inconvenience of warfarin and because the costs of warfarin plummeted after generic manufacturers entered the market, pharmaceutical companies saw an opportunity for profit so Defendants and other pharmaceutical manufacturers began the race to develop an alternative to warfarin.

26. The first novel oral anticoagulant approved in the United States was Pradaxa (dabigatran) in 2010, followed by Xarelto (rivaroxaban) in 2011, Eliquis (apixaban) in 2012, and Savaya (edoxaban) in 2015. Defendants received FDA approval to market Eliquis in 2012 (NDA 202155), and at all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Eliquis as a "new" or "novel" oral anticoagulant, also known as a Factor Xa inhibitor. Factor Xa is another factor on the coagulation cascade and forms the thrombin, which is required for blood to clot. By inhibiting

Factor Xa, Eliquis prevents thrombin from forming, which prevents blood from clotting.

27. Eliquis has two dosages—2.5 mg and 5 mg-- approved by the FDA to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. The FDA, in March 2014, expanded the indicated use for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients who have undergone hip or knee replacement. And in August 2014, the FDA label added that Eliquis is indicated for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. Among the uses for which Defendants obtained permission to market Eliquis was in the treatment of atrial fibrillation. Approval of Eliquis was based in large part on clinical trials known as ARISTOTLE.

28. The ARISTOTLE study was conducted under the supervision and control of Defendants in various countries including China. Defendants' agents committed fraud in their conduct of the ARISTOTLE study, by concealing side effects which occurred in test users of Eliquis; a death which went unreported (whereas one purpose of the study was to study the rate of death in Eliquis users compared to others in Coumadin); loss of subjects to follow up; major dispensing errors including indicating that certain subjects were getting Eliquis when they were not; poor overall quality control; and changing and falsifying records, including records disappearing just before the FDA made a site visit, reportedly on the order of an employee of BMS. Based upon information and belief, Defendants, as means of cutting costs, chose incompetent and untrustworthy agents in China to conduct the ARISTOTLE study.

29. The ARISTOTLE study was conducted under the supervision and control of Defendants in various countries including China. Defendants' agents committed fraud in their conduct of the ARISTOTLE study, by concealing side effects which occurred in test users of Eliquis; a death which went unreported (whereas one purpose of the study was to study the rate

of death in Eliquis users compared to others in Coumadin); loss of subjects to follow up; major dispensing errors including indicating that certain subjects were getting Eliquis when they were not; poor overall quality control; and changing and falsifying records, including records disappearing just before the FDA made a site visit, reportedly on the order of an employee of BMS. Based upon information and belief, Defendants, as means of cutting costs, chose incompetent and untrustworthy agents in China to conduct the ARISTOTLE study.

30. Sadly, Defendants and their agents committed fraud in their conduct of the ARISTOTLE study, by *inter alia,* concealing side effects that occurred in test users of Eliquis; concealing a death which went unreported (whereas one purpose of the study was to study the rate of death in Eliquis users compared to others on Coumadin); concealing loss of subjects to follow up; concealing major dispensing errors including indicating that certain subjects were getting Eliquis when they were not; having poor overall quality control; and changing and falsifying records, including records disappearing just before the FDA made a site visit, reportedly on the order of an employee of BMS (who was later terminated).

31. At a February 9, 2012 meeting between the FDA and BMS-Pfizer executives, the FDA is reported to have characterized the conduct of Defendants as showing a pattern of inadequate supervision.

32. Defendants market Eliquis as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. Defendants emphasize the alleged benefits of treatment with Eliquis over warfarin, in that Eliquis does not require periodic monitoring with blood tests, Eliquis did not limit a patient's diet, and Eliquis has a set dose that fits all patients.

33. When the application by defendants to the FDA was pending, in 2012, Dr. Thomas

Marcinak, a physician in the FDA who reviewed the data submitted by defendants in order to obtain approval to market Eliquis, objected to missing data from the ARISTOTLE study and recommended that the labeling which defendants were going to use with the drug should discuss the quality control problems in ARISTOTLE, the Chinese study. Dr. Marciniak concluded in a December 2012 memorandum that because vital data—primarily involving deaths—was missing from the trial, the data problems "destroy our confidence" that Eliquis reduces the risk of death.

34. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

35. Prior to Plaintiff's use of Eliquis and during the period in which Plaintiff actually used Eliquis, Defendants fraudulently suppressed material information regarding the safety and efficacy of Eliquis.

36. Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff, the FDA, and the public in general, that said product, Eliquis, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients required to take blood-thinning medications. Further, Defendants represented that the product had been adequately tested and evaluated in the ARISTOTLE study, and that the product was safe even though there was no reversal agent for the medication. Specifically, the fraudulent statements include, but are not limited to, the following:

a. Website – www.eliquis.com - https://www.eliquis.com/eliquis/hcp/stroke-risk-reduction-nvaf/efficacy - Defendants published "For patients with Nonvalvular Atrial Fibrillation (NVAF), Eliquis was proven effective in 2 Phase III studies." Defendants then cited to the "ARISTOTLE Study Primary Efficacy Endpoint" for justification of their representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to their highly flawed ARISTOTLE study.

Specifically, in the ARISTOTLE study sponsored by Defendants, there were unreported or late-reported serious side effects, and then one of Defendant's site managers instructed individuals to alter and otherwise falsify records. Additionally, per the FDA, [Defendant] BMS employees knew of these "irregularities" and then withheld their data from the global BMS team. Additionally, during the allegedly double-blind study, 7.3% of apixaban versus just 1.2% of the warfarin group were alleged to have received incorrect medications or placebos. All of their data was fraudulently submitted to the FDA, and then Defendants used their fraudulent data to misrepresent the effectiveness of Eliquis when citing to the ARISTOTLE study in support of its claims of the medication's efficacy.

b. Website:www.eliquis.com https://www.eliquis.com/eliquis/hcp/stroke- risk-reduction-nvaf - Defendants published that "ELIQUIS Is the *ONLY* anticoagulant that demonstrated superiority in *BOTH* stroke/systemic embolism and major bleeding vs warfarin . . . ARISTOTLE was a Phase III, randomized, multinational, double-blind trial of 18,201 nonvalvular atrial fibrillation patients (ELIQUIS, n=9,120; warfarin, n=9,081) with 1 or more additional risk factors for stroke. Defendants then cited to the ARISTOTLE Study for justification of their representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to their highly flawed ARISTOTLE study. Specifically, in the ARISTOTLE study sponsored by Defendants, there were unreported or late-reported serious side effects, and then one of Defendant's site managers instructed individuals to alter and otherwise falsify records. Additionally, per the FDA, [Defendant] BMS employees knew of these "irregularities" and then withheld their data from the global BMS team. Additionally, during the allegedly double- blind study, 7.3% of apixaban versus just 1.2% of the warfarin group were alleged to have received incorrect medications or placebos. All of their data was fraudulently submitted to the FDA, and then Defendants used their fraudulent data to misrepresent the effectiveness of Eliquis when citing to the ARISTOTLE study in support of its claims of the medication's efficacy.

c. Website – www.eliquis.com – as archived on September 2, 2013 – Defendants published that "Eliquis had less major bleeding than warfarin" and also cited that "unlike warfarin," there is no routine monitoring required. As part of the support for these representations, Defendants then cited to the ARISTOTLE Study for justification of their representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to their highly flawed ARISTOTLE study. Specifically, in the ARISTOTLE study sponsored by Defendants, there were unreported or late-reported serious side effects, and then one of Defendants' site managers instructed individuals to alter and otherwise falsify records. Additionally, per the FDA, [Defendant] BMS employees knew of these

"irregularities" and then withheld their data from the global BMS team. Additionally, during the allegedly double-blind study, 7.3% of apixaban versus just 1.2% of the warfarin group were alleged to have received incorrect medications or placebos. All of their data was fraudulently submitted to the FDA, and then Defendants used their fraudulent data to misrepresent the effectiveness of Eliquis when citing to the ARISTOTLE study in support of its claims of the medication's efficacy.

d. Dosing Guidelines – March 2014, as published by Defendants:

   i. Page 3 – "No dose adjustment required in patients with mild, moderate, or severe renal impairment alone" – Defendants intentionally misled prescribing physicians and consumers to believe that even with moderate or severe renal impairment, Eliquis was safe, when in fact, it was not appropriate for such patients;

   ii. Page 4 – "Does not require routine monitoring using international normalized ration (INR) or other tests of coagulation" – Defendants intentionally misled prescribing physicians and consumers to believe that no routine monitoring is necessary. However, given the extreme bleeding risk in patient populations (some of which were not adequately studied), monitoring is required for some or all patient populations;

   iii. Page 4 – While there is a section regarding the fact that "there is no established way to reverse the anticoagulant effect of apixaban, which can be expected to persist for at least 24 hours after the last dose," Defendants be deadly;

e. December 2012 – package insert for Eliquis, as published by Defendants –

   i. Section 2.2 – recommended dosage is false, as the patient characteristics were inappropriate and should have been limited to one characteristic, instead of two of the listed characteristics;

   ii. Section 5.2 – Bleeding. While there is a statement made that there is no reversal agent, Defendants withheld information and data that without the reversal agent, death could result;

f. March 2014 – package insert for Eliquis, as published by Defendants –

   i. Section 2.2 – recommended dosage is false, as the patient characteristics were inappropriate and should have been limited to one characteristic, instead of two of the listed characteristics; and

   ii. Section 5.2 – Bleeding. While there is a statement made that there is no

reversal agent, Defendants withheld information and data that without the reversal agent, death could result.

37. These representations were made by said Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular (including Dixie Walker's prescribing physicians), and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Eliquis, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

38. At the time the aforesaid representations were made by the Defendants and, at the time Plaintiff used Eliquis, Plaintiff and her prescribing physicians were unaware of the falsity of said representations and reasonably believed them to be true.

39. In reliance upon said representations, Plaintiff was induced to and did use Eliquis, thereby sustaining severe and permanent personal injuries. Further, Plaintiff's prescribing physicians also acted in reliance upon said misrepresentations.

40. Defendants knew and were aware, should have been aware, that Eliquis had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings. Moreover, Defendants knew or should have known that the recommended patient populations for dosing adjustments of Eliquis were inappropriate, and the failure to provide information that death can result from the lack of a reversal agent or the failure to monitor specific blood tests while on their medication is incomprehensible.

41. Defendants knew or should have known that Eliquis had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it w as inherently

dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

42. Defendants brought Eliquis to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

43. At the time Defendants concealed the fact that Eliquis was not safe, Defendants were under a duty to communicate their information to Plaintiff, physicians, the FDA, the healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Eliquis.

44. Defendants, at all times relevant hereto, withheld information from the FDA which they were required to report.

45. Plaintiff and her prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of Eliquis.

46. Plaintiff's prescribing physicians were not provided with the necessary information by the Defendants, to provide an adequate warning to Plaintiff.

47. Eliquis was improperly marketed to Plaintiff and Plaintiff's prescribing physicians as the Defendants did not provide proper instructions about how to use the medication (including, but not limited to, failing to properly adjust dose requirements for all consumers and for failing to state that the lack of a reversal agent was likely to cause serious injury or death) and thus did not adequately warn about Eliquis' risks.

48. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiff and Plaintiff's prescribing physicians, Defendants caused or contributed to Plaintiff's injuries (and ultimate death).

49. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiff. Despite their knowledge, the Defendants made conscious decisions

not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Eliquis. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from their type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

50. Defendants had a duty to disclose material information about serious side-effects to consumers such as Plaintiff.

51. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Eliquis as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in their Complaint. Defendants intentionally failed to disclose their information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

52. Had Plaintiff been aware of the hazards associated with Eliquis, Plaintiff would have employed appropriate blood monitoring, consumed a different anticoagulant with a better safety profile, or not have consumed the product that led proximately to Plaintiff's injuries.

53. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Eliquis, for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

54. The label fails to disclose other studies criticizing the results of ARISTOTLE study, including the findings regarding frequency and severity of bleeds on Eliquis.

55. Instead of admitting the major errors and frauds involved in the ARISTOTLE study, Defendants misleadingly stated publicly that they were submitting "additional data" to the

FDA, and to their date have never publicly acknowledged the missing and incorrect data submitted to the FDA, and to their date have never publicly acknowledged the missing and incorrect data submitted to the FDA, which would be of concern to prescribing physicians and the public.

56. After employees of defendants wrote and submitted an article based on the ARISTOTLE study for the New England Journal of Medicine, the article was reportedly attacked for its accuracy and omissions by the former editor-in-chief of that journal, Arnold Relman, M.D., including the failure to show that Eliquis was any more efficacious than low-cost warfarin.

57. Critically, there is no antidote to Eliquis, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available or validated reversal agent or antidote, as there is for Coumadin.

58. The U.S. label approved when the drug was first marketed in the U.S. and at the time Plaintiff was using it did not contain an adequate warning regarding the lack of antidote, and the significance of that problem for patients who began to bleed.

59. After the drug was approved by the FDA, Defendants engaged in an aggressive marketing campaign for Eliquis, including extensive marketing directly to the public, via TV and print. The chief promotional aspect of the sales pitch was that, unlike with Coumadin, the blood levels of the patient did not need to be monitored.

60. In the course of these direct-to-consumer advertisements, Defendants over promoted Eliquis as a "one-size-fits all dosage," overstated the efficacy of Eliquis with respect to preventing stroke and systemic embolism, overstated and misrepresented fact that Eliquis has less major bleeding than warfarin, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Eliquis, and that such irreversibility would have life-threatening and fatal consequences.

61. Defendants then stated publicly that they were submitting "additional data" to the FDA, and to their date have never publicly acknowledged the missing and incorrect data submitted to the FDA, which would be of concern to prescribing physicians and the public.

62. After employees of Defendants wrote and submitted an article based on the ARISTOTLE study for the New England Journal of Medicine, the article was reportedly attacked for its accuracy and omissions by the former editor-in-chief of that journal, Arnold Relman, M.D., including the failure to show that Eliquis was any more efficacious than low-cost warfarin.

63. Critically, there is no antidote/reversal agent to Eliquis available on the market, unlike Coumadin. Therefore, in the event of hemorrhagic complications, there is no available or validated reversal agent or antidote, as there is for Coumadin.

64. Prior to Plaintiff's use of Eliquis, Plaintiff became aware of the existence of Eliquis and its general claims, based upon her prescribing physician's recommendation of the use of their medication.

65. Based upon information and belief, prior to Plaintiff's use of Eliquis, Plaintiff's prescribing physician would have received promotional materials and information from sales representatives of Defendants that Eliquis was just as effective as warfarin (Coumadin) in reducing strokes in patients with non-valvular atrial fibrillation, and was more convenient, without also adequately informing prescribing physicians of potential risk of underdoing and overdoing due to the "one-size-fits-all" dosages, that there was no reversal agent that could stop or control bleeding in patients taking Eliquis, and overstated and misrepresented fact that Eliquis has less major bleeding than warfarin. Further, Defendants failed to adequately and accurately convey the length of time in which patients must be off of Eliquis prior to any procedure. Their pharmaceutical lacks an appropriate safety shield which has become a

standard in the pharmaceutical industry.

66. At all times relevant hereto, Defendants also failed adequately to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Eliquis, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Eliquis. Before and after marketing Eliquis, Defendants became aware of many reports of serious hemorrhaging in users of its drugs, both as reported to the FDA and to them directly. Yet Defendants have not fully disclosed to the medical profession or patients which the incidence of such adverse reactions are.

67. Despite the clear signal generated by the side effect data, Defendants failed to either alert the public and the scientific community or perform further investigation into the safety of Eliquis, both before and after approval.

68. Defendants' product labeling and prescribing information for Eliquis:

a. failed to investigate, research, study, and define, fully and adequately, the safety profile of Eliquis;

b. failed to provide adequate warnings about the true safety risks associated with the use of Eliquis;

c. failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Eliquis and its complete effects on the degree of anticoagulation in patients of various populations;

d. failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis;

e. failed to disclose in the "Warnings" section the significance of the fact that there is no drug, agent, or means to reverse the anticoagulation effects of Eliquis during an expanded timetable;

f. failed to advise prescribing physicians, such as the Plaintiff's physician, to

instruct patients that there was no agent to reverse the anticoagulant effects of Eliquis;

g. failed to provide adequate instructions on how to intervene and stabilize a patient who suffers a bleed while taking Eliquis;

h. failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Eliquis users;

i. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Eliquis, especially, in those patients with a prior history of gastrointestinal issues and upset;

j. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Eliquis and to continue testing and monitoring of renal functioning periodically while the patient is on Eliquis;

k. failed to advise physicians to monitor their patients closely for signs of neurological impairment (meaning a potential stroke);

l. failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Eliquis;

m. failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Eliquis and to continue testing and monitoring of hepatic functioning periodically while the patient is on Eliquis;

n. failed to include a "BOXED WARNING" about serious bleeding events associated with Eliquis;

o. failed to include a "BOLDED WARNNG" about serious bleeding events associates with Eliquis; Eliquis has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences;

p. failed to warn of the severity and duration of such adverse effects, as the warning given did not accurately reflect the symptoms or severity of side effects;

q. failed to warn regarding the need for more comprehensive, more regular

medical monitoring to ensure early discovery and potentially serious side effects; and

r. failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly and inaccurately that one dosage fit all patients.

69. As a result of Defendants' aggressive marketing efforts, it had sales of $774 million in 2014, of which $281 million was just for the fourth quarter alone. Eliquis has been referred to by the Defendants as a blockbuster drug. In support of its aggressive marketing, Defendants jointly paid more than $8 million to doctors in 2013, according to ProPublica/NY Times.

70. Despite life-threatening bleeding findings in clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Eliquis prior to filing their New Drug Application for Eliquis.

71. From the date Defendants received FDA approval to market Eliquis, Defendants made, distributed, marketed, and sold Eliquis without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Eliquis was associates with and could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Eliquis with regard to severe side effects, specifically life threatening bleeding.

72. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Eliquis was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

73. Defendants ignored the association between the use of Eliquis and the risk of developing life-threatening bleeding

74. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Eliquis for life-threatening bleeding risk further rendered warnings for their medication inadequate.

75. By reason of the foregoing acts and omissions, Plaintiff has endured and continues to suffer emotional and mental anguish, loss of support, loss of services, loss of earnings, medical expenses, and other economic and non-economic damages.

NEGLIGENCE STANDARD APPLIES TO ALL CAUSES OF ACTION UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

76. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads their Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to their case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

77. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Eliquis including a duty to assure that the product did not cause unreasonable, dangerous side-effects to users.

78. Defendants failed to exercise ordinary care in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Eliquis in that Defendants knew, or should have known, that the drugs created a high risk of unreasonable, dangerous side-effects and harm, including life-threatening bleeding, as well as other severe and personal injuries, Dixie Walker suffered physical pain and mental anguish, and diminished enjoyment of life. Further, Defendants were well aware that if dosing instructions

were not properly adjusted for age and information. Defendants' failure to provide a reasonably safe pharmaceutical, and Defendants' failure to adequately instruct or warn the users of the aforementioned dangers was negligent. Plaintiff's injuries and damages were a foreseeable, direct and proximate result of the negligence of Defendants.

79. Defendants, their agents, servants, and/or employees were negligent in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Eliquis in that, among other things, they:

a. Failed to use due care in designing and manufacturing, and testing Eliquis (before placing it on the market) so as to avoid the aforementioned risks to individuals;

b. Failed to analyze pre-marketing test data of Eliquis and convey the true risks of Eliquis based on the results of the testing conducted prior to placing Eliquis on the market;

c. Failed to conduct sufficient post-marketing and surveillance of Eliquis in order to provide updated information to providers and patient populations;

d. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects, as well as the significance of the lack of a reversal agent for Eliquis. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects; the warnings given did not warn Plaintiff and their healthcare providers regarding the need for blood monitoring, appropriate dose adjustments for various consumer groups, and further failed to fully and appropriately warn of the risk of serious bleeding that may be irreversible, and life-threatening, associated with Eliquis;

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

f. Falsely and misleadingly over promoted, advertised and marketed Eliquis as set forth herein including overstating efficacy, minimizing risk to influence patients, such as Plaintiff, to purchase and consume such product;

g. Manufacturing, producing, promoting, formulating, creating, and/or designing Eliquis without thoroughly testing it;

h. Manufacturing, producing, promoting, formulating, creating, and/or;

i. Not conducting sufficient testing programs to determine whether or not Eliquis was safe for use; in that Defendants herein knew or should have known that Eliquis was unsafe and unfit for use by reason of the dangers to its users;

j. Selling Eliquis without making proper and sufficient tests to determine the dangers to its users;

k. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Eliquis;

l. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Eliquis;

m. Failing to adequately, sufficiently and properly test Eliquis;

n. Negligently advertising and recommending the use of Eliquis without sufficient knowledge as to its dangerous propensities;

o. Negligently representing that Eliquis was safe for use for its intended purpose, when, in fact, it was unsafe;

p. Negligently representing that Eliquis had equivalent safety and efficacy as other forms of treatment for patients taking blood-thinning medication;

q. Negligently designing Eliquis in a manner which was dangerous to its users;

r. Negligently manufacturing Eliquis in a manner which was dangerous to its users;

s. Negligently producing Eliquis in a manner which was dangerous to its users;

t. Concealing information from Plaintiff showing that Eliquis was unsafe, dangerous, and/or non-conforming with FDA regulations;

u. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals (including Dixie Walker's prescribing physicians), and/or the FDA, concerning the severity of risks and dangers of Eliquis compared to other forms of treatment for blood-thinning; and,

v. Placing an unsafe product into the stream of commerce.

80. Defendants under-reported, underestimated and downplayed the serious dangers of Eliquis.

81. Defendants negligently compared the safety risk and/or dangers of Eliquis with other forms of treatment of blood thinners.

82. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Eliquis in that they:

a. Failed to use due care in designing and manufacturing Eliquis so as to avoid the aforementioned risks to individuals;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Eliquis;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Eliquis;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Eliquis;

e. Failed to warn Plaintiff and/or her physician of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Eliquis;

g. Failed to warn Plaintiff and/or her physician, prior to actively encouraging the sale of Eliquis, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual or of the risks of hemorrhagic events to ensure early discovery of potentially serious side effects;

h. Failed to provide full and appropriate dosing guidelines for all consumer groups;

i. Failed to warn that the lack of a reversal agent was likely to cause injury or death

j. Were otherwise careless and/or negligent.

83. Despite the fact that Defendants knew or should have known that Eliquis caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market Eliquis to consumers, including the medical community and Plaintiff.

84. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

85. It was foreseeable that Defendants' product, as designed, would cause serious injury to consumers, including Plaintiff.

86. As a direct and proximate result of Defendants' negligence, DIXIE WALKER suffered serious physical injury, harm, and Plaintiff will continue to suffer damages and economic loss in the future. Defendants are jointly and severally liable in negligence for Plaintiff's injuries and for general and special damages proximately caused by such negligence, in such amounts as shall be determined at trial.

87. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed their knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting consuming public. Defendants' outrageous conduct constitutes gross negligence which warrants an award of punitive damages.

FIRST CAUSE OF ACTION
PRODUCT LIABILITY – DESIGN DEFECT UNDER LA. R.S. 9:2800.56

88. Plaintiff incorporates by reference each preceding and succeeding paragraph as

though set forth fully at length herein. Plaintiff pleads their Count in the broadest sense possible, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State

89. Defendants had a products liability duty to design, manufacture, and market products, including Eliquis, that were not unreasonably dangerous or defective, but which were safe for their users, including Plaintiff. Defendants also had a products liability duty to provide adequate warnings and instruction for use regarding Eliquis. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug Eliquis was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

90. Defendants, failed to exercise ordinary care in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Eliquis in that Defendants knew or should have known that the drugs created a high risk of unreasonable, dangerous side-effects and harm, including life-threatening bleeding, as well as other severe and personal injuries (including in some cases death) which are permanent and lasting in nature, physical pain, mental anguish, including diminished enjoyment of life.

91. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Eliquis as hereinabove described that was used by the Plaintiff.

92. Defendants' Eliquis was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff, without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

93. At those times, Eliquis was in an unsafe, defective, and inherently dangerous

condition, which was unreasonably dangerous to users for its intended or reasonably foreseeable use, and in particular, the Plaintiff herein.

A. Design Defect

94. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads their Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to their case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

95. At all times material to their action, Eliquis was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Eliquis contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to permanent, personal, life-threatening injuries;

b. When placed in the stream of commerce, Eliquis was defective in design and formulation, making the use of Eliquis more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market;

c. Eliquis' design defects existed before it left the control of the Defendants;

d. Eliquis was insufficiently tested;

e. Eliquis caused harmful side effects that outweighed any potential utility;

f. Eliquis was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff; and

g. A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

96. When it left the control of Defendants, Eliquis was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

97. Eliquis was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or applicable federal requirements, and posed a risk of serious injury and death. There were conditions of Eliquis that rendered it unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use.

98. Specifically, Eliquis was more likely to cause serious bleeding that may be irreversible, permanently disabling, and life-threatening more so than other anticoagulants as to patients in certain patient populations, including those with renal compromise, of a certain age and of certain weight. Additionally, Eliquis was designed with no reversal agent, so that in the event of a hemorrhagic bleed, there would be no method to reverse the bleeding, thus causing a potentially fatal bleeding episode. At all times herein mentioned, Eliquis was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

99. Eliquis as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Eliquis, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and promote their product, Eliquis.

100. Eliquis was more likely to cause serious bleeding that may be irreversible, permanently disabling, and life-threatening more so than other anticoagulants.

101. The design defects render Eliquis more dangerous than other anticoagulants and cause an unreasonable increased risk of injury, including but not limited to life-threatening bleeding events.

102. The nature and magnitude of the risk of harm associated with the design of Eliquis, including risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening is high in light of the intended and reasonably foreseeable use of Eliquis.

103. The risk of harm associated with the design of Eliquis are higher than necessary.

104. It is highly unlikely that Eliquis users and their prescribing physicians would be aware of the risks associated with Eliquis through either warning, general knowledge, or otherwise.

105. The intended or actual utility of Eliquis is not of such benefit to justify the risk of bleeding that may be irreversible, permanently disabling, and life-threatening.

106. Plaintiff used Eliquis in substantially the same condition it was in when it left the control of Defendants and any changes or modifications were foreseeable by Defendants.

107. Plaintiff and her healthcare providers did not misuse or materially alter their Eliquis.

108. As a direct and proximate result of the use of Eliquis, Plaintiff, DIXIE WALKER, suffered serious physical injury, harm, damages and economic loss, and Plaintiff will continue to suffer such harm, damages and economic loss in the future.

109. Defendants placed Eliquis into the stream of commerce with wanton and reckless disregard for public safety.

110. Eliquis was in an unsafe, defective, and inherently dangerous condition. Eliquis contains defects in its design which render the drug dangerous to consumers, such as Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render Eliquis more dangerous than other anticoagulants and cause an unreasonable increased risk of injury, including but not limited to life-threatening bleeding events.

111. Eliquis was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that Eliquis was defective and unsafe, even when used as instructed.

112. The nature and magnitude of the risk of harm associated with the design of Eliquis, including the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening is high in light of the intended and reasonably foreseeable use of Eliquis.

113. It is highly unlikely that Eliquis users would be aware of the risks associated with Eliquis through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks, nor would Plaintiff have expected them.

114. The design did not conform to any applicable public or private product standard that was in effect when Eliquis left the Defendants' control.

115. Eliquis' design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

116. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Eliquis as to certain users/patient populations,

including but not limited to the following:

a. a dangerous one-size fits almost all approach to doing instructions. For any separation of patient populations, it was grossly inaccurate and not representative of the true bleeding risks and dosage needs for these populations;

b. Failure to have tests available to determine and demonstrate therapeutic range;

c. Failure to advise testing for therapeutic range;

d. Failure to provide a therapeutic range; and

e. Failure to recommend testing and/or monitoring by providers for therapeutic range.

117. At all times herein mentioned, Eliquis was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants. Improper dosing instructions resulted in patients like plaintiff, DIXIE WALKER becoming hyper-coagulated (excessive coagulation) causing serious bleeding.

118. Defendants knew, or should have known that at all times herein mentioned, their Eliquis was in a defective condition, and was and is inherently dangerous and unsafe.

119. At the time of Plaintiff's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended, and specifically for atrial fibrillation patients as an alternative to Warfarin. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff. The improper dosing led to patients like Plaintiff, DIXIE WALKER, becoming hyper-coagulated (excessive coagulation), causing serious bleeding.

120. Plaintiff could not, by the exercise of reasonable care, have discovered Eliquis' defects herein mentioned and perceived its danger.

121. There was a safer alternative design for Eliquis available at the time of manufacture. Their safer alternative design would have prevented or significantly reduced the risk of the injury and death in question without substantially impairing the product's utility and the safer alternative design was economically and technologically feasible at the time Eliquis left control of Defendants, by the application of existing or reasonably achievable scientific knowledge. A safer alternative design of Eliquis would have included, *inter alia,* a proper therapeutic range of dosing, a recommended regime of monitoring/testing, availability of an effective reversal agent, and proper instructions on the half-life of Eliquis and how long it must be discontinued before surgery.

122. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed their knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages. Defendants knew marketing the drug without knowing the safe therapeutic level for all consumers would likely cause injury. To their end, Defendants published a paper showing 43 percent more exposure to the drug for those with creatinine levels at 1.5 or above, yet failed to properly supply adjusted dosing information. Thus, Defendants knowingly put a group of consumers at risk, while Defendants knew that placing their drug on the market with dosing instructions not properly adjusted for age and co-morbidities of certain consumers would likely cause injury. Defendants further knew or should have known that three (3) days was not an adequate amount of time to

discontinue Eliquis prior to major surgery.

123. The unreasonably dangerous nature of Eliquis caused serious harm to Plaintiff.

124. These aforementioned design defects in Defendants' drug Eliquis were a proximate cause of Plaintiff's injuries. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

SECOND CAUSE OF ACTION
PRODUCT LIABILITY – FAILURE TO WARN UNDER LA. R.S. 9:2800.57

125. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads their Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to their case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law. Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Eliquis

a. Defendants failed to warn and place adequate warnings and instructions on Eliquis;

b. Defendants failed to adequately give ***correct*** dosing instructions for different ages, renal impairments and weights, and instead gave inadequate dosing instructions for those populations;

c. Defendants failed to provide proper information as to the half-life of Eliquis and the amount of time that Eliquis should be discontinued prior to surgery;

d. Defendants failed to provide proper warnings that the lack of a reversal agent can cause death; and

e. Defendants failed to warn of the fraud and irregularities which occurred

> during the testing of Eliquis during the ARISTOTLE drug trials, and how such irregularities makes Defendants' data and claims unreliable.

126. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiff for the marketing, promoting, distribution, and selling of a defective product, Eliquis, which Defendants placed on the market without adequate warnings. Defendants breached their duties by failing to provide a reasonably safe pharmaceutical and adequately warn of same. By virtue of the foregoing, Defendants are jointly and severally liable for Plaintiff's injuries.

127. Defendants' inadequate warnings of Eliquis were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

128. These aforementioned warning defects in Defendants' drug Eliquis were a proximate cause of Plaintiff's injuries.

129. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care all suffered or incurred knowledge of the safety and efficacy problems and suppressed their knowledge from the general public regarding the true risks of bleeding in different population. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

THIRD CAUSE OF ACTION
(REDHIBITION)

130. Pursuant to Article 2520 of the Louisiana Civil Code:

> The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known

> of the defect. The existence of such a defect gives a buyer the right to obtain rescission of the sale. A defect is redhibitory also when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price. The existence of such a defect limits the right of a buyer to a reduction of the price.

131. The danger to people including Plaintiffs resulting from the redhibitory defects and/or vices related to Eliquis was foreseeable by Defendants. Eliquis contains redhibitory defects and/or vices and damaged Plaintiffs.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY UNDER LA. R.S. 9:2800.58

132. Pursuant to La. R.S. 9:2800.58, "A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue."

133. The danger to people including Plaintiffs resulting from the failure to conform to express warranties related to Eliquis was foreseeable by Defendants.

134. Eliquis is unreasonably dangerous because they did not conform to express warranties pursuant to La. R.S. 9:2800.58 and damaged Plaintiffs.

EIGHTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)
(EMOTIONAL DISTRESS AND LOSS OF ENJOYMENT OF LIFE)

135. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

136. Plaintiff, CHARLES WALKER, was at all times relevant hereto the spouse of Plaintiff, and as such, lived and cohabitated with him.

137. By reason of the foregoing, Plaintiff, CHARLES WALKER, has incurred significant expenses for medical care and will continue to be economically and emotionally harmed in the future.

138. By reason of the foregoing, Plaintiffs were caused to suffer, and Plaintiffs will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

JURY TRIAL DEMANDED

139. Plaintiffs demand that all issues of fact of their case be tried to a properly impaneled jury to the extent permitted under the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages available by law or statute in an amount to be determined at trial of their action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages paid or owed by Plaintiff in an amount to be determined at trial of their action;

3. Prejudgment interest;

4. Post-judgment interest;

5. Awarding Plaintiff the costs of these proceedings; and

Such other and further relief as their Court deems just and proper.

Dated: October 28, 2016

RESPECTFULLY SUBMITTED,

By:/s/ Lisa Causey-Streete

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JS 44 (Rev. 11/15)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

DIXIE WALKER and CHARLES WALKER

(b) County of Residence of First Listed Plaintiff St. Tammany Parish, LA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Lisa Causey-Streete, SALIM-BEASLEY, LLC
1901 Texas Street, Natchitoches, LA 71457
800-491-1817

DEFENDANTS

BRISTOL-MYERS SQUIBB and PFIZER, INC.

County of Residence of First Listed Defendant New Castle County, DE
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal Injury; Product Liability

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
10/28/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Lisa Causey-Streete

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

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

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

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

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

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

DIXIE WALKER and CHARLES WALKER

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC.

Defendant(s)

Civil Action No. 2:16-cv-15940

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BRISTOL-MYERS SQUIBB CO
C/O CT CORPORATION
111 8TH AVENUE
NY NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lisa Causey-Streete
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:16-cv-15940

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 $ 0.00 .

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:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

DIXIE WALKER and CHARLES WALKER

Plaintiff(s)

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC.

Defendant(s)

Civil Action No. 2:16-cv-15940

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C/O CT CORPORATION
111 8TH AVENUE
NY NY 10011

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SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:16-cv-15940

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❒ 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

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My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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Date: _____

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Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: