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Case No. N18C-01-019 AML

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

EDWARD OLIVER, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC., Defendants.	C.A. No.: JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, the above-captioned Plaintiff, EDWARD OLIVER (hereinafter, "Plaintiff") brings this complaint and Demand for Jury Trial by and through his attorneys JACOBS & CRUMPLAR, P.A., and complains and alleges against Defendants Bristol-Myers Squibb Company and Pfizer Inc. ("Defendants") as follows:

SUMMARY OF ALLEGATIONS

1. This is a products liability action against the Defendants because Plaintiff as a direct and proximate result of Defendants' conduct, suffered and incurred harm including severe pain and suffered personal injuries and incurred damages to include severe pain and suffering, medical expenses and other economic and noneconomic damages.

2. Defendants, BRISTOL-MYERS SQUIBB COMPANY 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.

3. 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 indicative uses.

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

5. These representations were made by Defendant 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.

6. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including life-threatening bleeding, physical pain and mental anguish, including diminished enjoyment of life and shortened life expectancy.

7. All Plaintiff in this action seek recovery for damages in an amount less than $75,000.00 as a result of developing severe bleeding events, which was directly and proximately caused by such wrongful conduct by Defendants, the unreasonably dangerous and defective nature of the Eliquis, and the attendant effects of developing severe, irreversible bleeding as a result of ingesting Eliquis. All of the claims involve common legal and medical issues.

8. At all relevant times, all Defendants were engaged in the research, development, manufacture, design, testing, sale and marketing of Eliquis, and introduced such products into

interstate commerce with knowledge and intent that such products be sold in all States, including but not limited to the State of Delaware.

9. Defendants concealed and continue to conceal their knowledge of the unreasonably dangerous risks of Eliquis from Plaintiff, other consumers, and the medical community. Specifically, Defendants failed to adequately inform Plaintiff, consumers, and the medical community about the known risks of severe, irreversible bleeding associated with the use of Eliquis.

PARTY PLAINTIFF

10. Plaintiff EDWARD OLIVER, is a competent individual over the age of 18 currently residing in Pennsylvania and hereby submits to the jurisdiction of this Court and alleges the Venue is proper. Mr. Oliver regularly used Defendants' Eliquis and suffered from severe physical, economic and emotional injuries as a result of his use of Defendants' Eliquis, including but not limited to gastrointestinal bleeding diagnosed in January 2016.

PARTY DEFENDANTS

11. Defendant BRISTOL-MYERS SQUIBB COMPANY ("BMS") is a company organized under the laws of Delaware with a principal place of business at 345 Park Avenue, New York, New York. Its registered agent for service of process is: c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Defendant BMS is the holder of the approved New Drug Application ("NDA") for Eliquis as well as the supplemental NDA.

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

13. 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.

14. Defendant PFIZER INC. ("Pfizer") is and, at all relevant times was, a corporation organized under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New York. Its registered agent for service of process is: c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

15. 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.

16. 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 this field."

FACTUAL BACKGROUND

17. Eliquis is in a class of drugs known as oral anticoagulants. Coagulation, also known as clotting, is the process by which blood changes from a liquid to a gel forming a blood clot. This process is referred to as the coagulation cascade, and is the sequence in which platelets, proteins, and others substances in the blood react to a triggering event that culminates in clot formation.

18. Anticoagulants are a class of drugs commonly used to prevent the blood from forming dangerous clots that could result in a stroke and are often called blood thinners. Oral anticoagulants are available for the prophylaxis and treatment of thromboembolic disease,

including the acute treatment and secondary prophylaxis for venous thromboembolisms (VTEs) and the risk reduction of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). Atrial fibrillation occurs when one or both of the upper chambers of the heart-called the atria-beat erratically. Atrial fibrillation normally causes only a modest reduction in cardiac output. But in the "dead zone" of the malfunctioning atria, blood clots may form and then travel to the lungs or brain, where irreversible and potentially life-threatening damage may occur. Treatment includes the well-established vitamin K antagonist (VKA), warfarin, and newer agents such as direct thrombin inhibitor, Pradaxa (dabigatran etexilate), and the direct factor Xa inhibitors Xarelto (rivaroxaban), Eliquis (apixaban), and Savayasa (edoxaban). These newer classes of drugs are known as either novel or direct oral anticoagulants (DOACs or NOACs) because their mechanisms of action involve direct inhibition of specific serine proteases in the coagulation cascade, whereas VKAs indirectly inhibit several steps in the cascade.

19. Warfarin is a long-established safe treatment for preventing stroke and systemic embolism. Since 1954, warfarin has been prescribed for its anticoagulation effect. Vitamin K is used by multiple clotting factors to help the blood clot, and warfarin inhibits certain clotting factors that rely on Vitamin K within the coagulation cascade.

20. BMS distributes the brand-name Coumadin (warfarin sodium), and several other manufacturers distribute generic equivalents. The Coumadin label, in bold, all caps, and in Black Box[1] warns:

WARNING: BLEEDING RISK

See full prescribing information for complete boxed warning.

- **COUMADIN can cause major or fatal bleeding. (5.1)**
- **Perform regular monitoring of INR in all treated patients. (2.1)**
- **Drugs, dietary changes, and other factors affect INR levels achieved with COUMADIN therapy. (7)**

[1] A "black box warning" is designed to call attention to serious or life-threatening risks.

- **Instruct patients about prevention measures to minimize risk of bleeding and to report signs and symptoms of bleeding. (17)**

21. The Coumadin label further explains that dosage is individualized in accordance with each patient's International Normalized Ratio (INR) response to the drug, and patient's must be monitored carefully to ensure the dose given is therapeutic for the patient. Based on the test results, the warfarin dose is adjusted based on the patient's INR and the condition treated.

22. To test a patient's INR, clinicians may use a variety of laboratory tests that measure the time taken for a plasma sample to form a clot after the addition of calcium and an activator.[2] A high INR indicates a high risk of uncontrollable bleeding; a low INR indicates a high risk for blood clots.

23. In the event of a bleeding event 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 a well-established drug, Warfarin has some drawbacks, including frequent monitoring, strict dietary restrictions, and interacts (negatively) with other drugs. Every few weeks, a patient on warfarin must have his blood drawn to measure the INR, i.e., the time it takes for a clot to form. In addition, patients taking warfarin must follow a strict diet to avoid foods that contain a high amount of vitamin K, which includes green leafy vegetables. Warfarin, although safe and effective, is inconvenient.

25. Given the inconvenience of warfarin and because the costs of warfarin

[2] Notably, these tests are not specific to any particular anticoagulant.

plummeted after generic manufacturers entered the market, pharmaceutical companies saw an opportunity and began the race to develop an alternative to warfarin.

26. Boehringer Ingelheim Pharmaceuticals, Inc. won the race to develop an alternative option to warfarin with the approval of Pradaxa (dabigatran) in October 2010 by the United States Food and Drug Administration (FDA), and others followed shortly thereafter, including Xarelto (rivaroxaban) in 2011, Eliquis (apixaban) in 2012, and Savaya (edoxaban) in 2015.

27. These NOACs are designed to inhibit specific single targets in the coagulation cascade. Pradaxa is a direct thrombin inhibitor (Factor IIa); Xarelto, Eliquis, and Savaya directly inhibit Factor Xa. Directly targeting these specific factors results in an anticoagulation effect for the duration of time the medication remains in a patient's system.

28. Undisputedly, these medications, comparable to warfarin, have a high-risk bleeding, including fatal bleeding. Only Pradaxa has a specific reversal agent (idarucizumab) to reverse the anticoagulation effect in the event an emergency surgery / urgent procedure is needed or in the event of a life-threatening or uncontrolled bleeding. The lack of a reversal agent for the Factor Xa inhibitors is a major concern, and late-phase clinical trials of reversal agents are currently ongoing.

29. On December 28, 2012, the FDA approved Eliquis to reduce the risk of stroke and blood clots in patients with non-valvular atrial fibrillation. ((NDA 202155). On March 8, 2014, the FDA approved the supplemental new drug application for Eliquis to reduce the risk of blood clots following hip or knee replacement surgery based on the ADVANCE clinical trial program comparing Eliquis to enoxaparin to assess the safety and efficacy of Eliquis, and on August 21, 2014, the FDA approved Eliquis for the treatment of deep vein thrombosis and pulmonary embolism based on AMPLIFY and AMPLIFY-EXTENSION trials.

30. Eliquis is available in two doses—2.5 mg and 5 mg—to be taken twice daily.

31. The safety and efficacy of Eliquis in treating patients with non-valvular atrial fibrillation was studied in a clinical trial, known as ARISTOTLE, that compared Eliquis with

warfarin and AVERROES, which compared Eliquis with aspirin in patients who had at least one additional risk factor for stroke and had not responded to or were unsuitable for vitamin K antagonist therapy.

32. Defendants BMS and Pfizer, in the race to gain FDA approval over competitors, committed major errors in the ARISTOTLE study. The ARISTOTLE study was conducted under the supervision and control of defendants, in various countries, including China. Defendants BMS and Pfizer, as means of cutting costs, chose incompetent and untrustworthy agents in China to conduct the ARISTOTLE study. These 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. At a February 9, 2012 meeting between the FDA and BMS-Pfizer executives, the FDA is reported to have characterized the conduct of BMS and Pfizer as showing a pattern of inadequate supervision.

33. When the application by BMS and Pfizer to the FDA was pending, in 2012, Dr. Thomas Marciniak, a physician in the FDA who reviewed the data submitted in order to obtain approval to market Eliquis, objected to missing data from the ARISTOTLE study and recommended that the labeling discuss the quality control problems in ARISTOTLE, the Chinese study. Instead of admitting the major errors and frauds involved in the ARISTOTLE study, BMS and Pfizer misleadingly stated publicly that they were submitting "additional data" to the FDA, and to this 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. Many doctors, in fact, would not prescribe Eliquis if they knew that the clinical trials supported approval were unreliable or were missing critical information.

34. After employees of defendants BMS and Pfizer 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.

35. On March 8, 2014, the FDA approved the supplement new drug application for Eliquis to reduce the risk of blood clots following hip or knee replacement surgery based on the ADVANCE clinical trial program comparing Eliquis to enoxaparin to assess the safety and efficacy of Eliquis. And on August 21, 2014, the FDA approved Eliquis for the treatment of deep vein thrombosis and pulmonary embolism based on AMPLIFY and AMPLIFY-EXTENSION trials.

36. All phase III clinical trials claiming that Eliquis is superior to aspirin or warfarin and is associated with less bleeding are sponsored by BMS and Pfizer. But independent medical reviews and meta-analysis show that Eliquis is inferior to the vitamin K antagonists class in preventing ischemic strokes and is associated with a higher incidence of uncontrolled minor and major bleeding leading to death. BMS, Pfizer, and McKesson either have failed to evaluate these studies and meta-analysis, or have ignored it since the labeling of Eliquis has not been updated.

37. In fact, adverse event reports and hospitalizations due to bleeding events rise as Eliquis gains market share**.** Eliquis, on the market for just five years, is the second most prescribed NOAC. Among the new agents, rivaroxaban (Xarelto) led, with 17.5% of dispensed outpatient prescriptions, but apixaban (Eliquis) prescriptions increased four-fold over the time period and now account for 19.2% of dispensed outpatient prescriptions. From 2015Q4 to 2016Q4, Eliquis prescriptions between 2015 and 2016 increased by 66%.

38. As Eliquis gains market share, post-marketing surveillance is crucial for estimating and characterizing Eliquis-related harms in clinical practice or "real world" settings, especially since the drug company sponsored clinical trials used for evaluating the safety profile

of Eliquis undisputedly excluded populations at the highest risk for adverse events.

39. Although Eliquis has been on the market a relatively short time, Eliquis accounts for the second largest number of serious injuries and death in the United States through the last quarter of 2016, according to the FDA Adverse Event Reporting System (FAERs) database. Practically, all reported injuries or death due to Eliquis were from hemorrhages, including 8,495 gastrointestinal bleeds and nearly 2,000 cerebral bleeds. More than 1,000 adverse event reports were filed with the FDA in 2014 alone, including at least 100 deaths, and more than 6,000 Eliquis adverse event reports in 2015 consisted of predominantly hemorrhaging / gastrointestinal hemorrhaging.

40. The number of major bleeding events and death due to the increasing number of Eliquis prescriptions will continue climb as Eliquis gains market share.

41. According to a recently published study from the Center for Disease Control (CDC) on emergency department visits from 2013 to 2014, anticoagulants accounted for nearly 18% of all Emergency Department (ED) visits, with 48% overall requiring hospitalization. Based on those numbers, the QuarterWatch estimates that nearly seven percent of patients exposed to anticoagulants for one year will require an Emergency Department visit due to a bleed. Eliquis has continued to gain market share since the 2014 cut-off date of the CDC study; which correlates to more Eliquis related bleeds.

42. Clinical studies from the "real world" clinical practice show Eliquis as compared with warfarin is associated with a trend towards higher rates of ischemic stroke / systemic embolism compared with warfarin, and bleeding events for Eliquis as compared with warfarin were higher or not significantly different.

43. Other independent studies, i.e., not sponsored by BMS and Pfizer, document in the medical reviews and meta-analysis that Eliquis is equal or inferior to warfarin and has an increased incidence of minor and major bleeding, which in some instances, was fatal.

44. Defendants failed to perform a systematic meta-analysis and or signal investigation from all of the available evidence.

45. Before and after marketing Eliquis, defendants BMS, Pfizer, and McKesson became aware of many reports of serious hemorrhaging in users of its drugs, both as reported to the FDA and to it directly. Yet these Defendants have never disclosed to the medical profession or patients what the incidence of such adverse reactions are.

46. Despite the clear signal generated by the side effect data, Defendants BMS, Pfizer, and McKesson failed to either alert the public and the scientific community, or perform further investigation into the safety of Eliquis.

47. Despite being inferior to warfarin with respect to both safety and Eliquis, BMS, Pfizer, and McKesson, Defendants selling point for Eliquis is that it is better for warfarin and more convenient because of minimal medication and food interactions and fixed, twice daily dosing without the need for routine monitoring of coagulation status.

48. But monitoring and measuring the drug levels of Eliquis or the anticoagulation effect is necessary to effectively manage patients with serious bleeding or thrombolic events, establish optimal timing for surgery or other invasive procedures, to detect drug accumulation in the case of acute renal or hepatic insufficiency or suspected overdose, identify subtherapeutic or supratheraputic levels in patients taken other drugs, and identify subtherapeutic or therapeutic levels in patients that are overweight or have renal or hepatic insufficiency. Accordingly, Defendants should have designed a specific assay before sending Eliquis to the FDA for approval. In fact, Europe already approved a specific testing solution for the measurement of Eliquis that may be used in numerous situations, including when the emergency room with an adverse event or require verification of pre-operative drug clearance.

49. In the alternative, Defendants should have included a reference to commercially available monitoring and laboratory testing such as PT, INR, aPTT, dPTT, or Rotachrom testing that could be used to monitor the effects of anticoagulation or drug levels in the Warnings Section of its label.

50. Defendants label should have included a warning that doctors should have used Eliquis in certain patient populations only as a last resort given Defendants knowledge that

certain patient populations were at an increased risk of a major bleeding event.

51. Defendants' label should have included a warning that doctors should not have prescribed Eliquis in certain patient populations, including, for example, those patients who had a bleed in the past or other medical conditions that may the patient more vulnerable to a serious adverse reaction on Eliquis.

52. Nor do Defendants warn the prescribing physicians that they need to closely monitor their patients for signs and symptoms of bleeding, neurological deficits, or the sufficiency of their renal or hepatic function. If a patient's renal function worsens while on Eliquis, for example, the Eliquis concentrations will increase with each doses, leaving a patient susceptible to a bleed.

53. Instead, 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 warfarin, the blood levels of the patient did not need to be monitored.

54. From 2013 to present, Defendants aired several direct to consumer television advertisements, including, but not limited to, the "Bringing my Best," "Fisherman," "No Matter Where I Ride," and "Go for My Best" spots, all of which portray Eliquis as the "best" treatment for Afib and importantly, a better and safer alternative to Warfarin with no requirement for routine blood testing. In these advertisements, Defendants neglected to mention that there is no reversal agent for Eliquis or ability to monitor or test anticoagulation in the event of an emergency. These ads were designed to influence patients, including the Plaintiff, to make inquiries to their prescribing physician about Eliquis and/or to request prescriptions for Eliquis. These ads overstated that Eliquis has less major bleeding risk and less stroke risk than warfarin, downplayed the risk and 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 could have life-threatening and fatal consequences as well as failed to disclose to patients that there is no

ability to monitor the anticoagulation effects or drug concentration levels in the event of a medical emergency or life-threatening bleed.

55. 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

56. Defendants in their labeling and marketing material downplay the risk of a worse outcome on Eliquis in the event of a bleeding event due to the lack of a reversal agent or ability to monitor to level of anticoagulation in a medical emergency. Defendants' marketing materials suggest that Eliquis represents a therapeutic simplification and therapeutic progress of anticoagulation therapy because it does not require dosage adjustments, does not requires patients to undergo periodic monitoring with blood tests and because there were no dietary restrictions.

57. In the course of these direct-to- consumer advertisements, Defendants overstated the efficacy of Eliquis with respect to preventing stroke and systemic embolism, 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.

58. Defendants over promoted Eliquis as having simply two available dosages, 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.

59. McKesson Corporation played a key role in marketing, distributing, and selling Eliquis to California residents and nationwide. In fact, both BMS and Pfizer list McKesson

Corporation, in its role as a wholesale distributor for its pharmaceutical products, as a top revenue generator for their companies.

60. Prior to Plaintiff's use of Eliquis, Plaintiff became aware of the promotional materials described herein from sales representatives of Defendants that Eliquis was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Eliquis, without also adequately informing prescribing physicians of potential risk of under-dosing and overdosing due to the fixed dosages, that there was no reversal agent that could stop or control bleeding in patients taking Eliquis, there was no ability to monitor the anticoagulation effect or drug concentration levels, overstated and misrepresented fact that Eliquis has less major bleeding than warfarin, and overstated and misrepresented the therapeutic benefit of the drug. Further, Defendants failed to adequately and accurately convey the length of time in which patients must be off of Eliquis prior to any procedure. This pharmaceutical lacks an appropriate safety shield which has become a standard in the pharmaceutical industry.

61. Prior to Plaintiff's use of Eliquis, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Eliquis was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, and was more convenient for the reason, *inter alia*, that no monitoring was required, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Eliquis and such irreversibility would have life-threatening and fatal consequences.

62. Defendants, prior to submitting Eliquis for FDA approval, should have designed an antidote for FDA approval. Moreover, the label did not contain an adequate warning regarding the lack of antidote, and the significance of that problem for patients who began to bleed.

63. 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. Equally as important, the labeling failed to warn health care providers that commercially available laboratory tests and assays could mitigate the risk of bleeding.

64. 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 effects on the degree of anticoagulation in a patient;

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 adequately disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis;

f. failed to advise prescribing physicians, such as the Plaintiff's physicians, 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 increased risk of suffering a bleeding event, requiring blood transfusions in those taking Eliquis;

k. 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;

l. 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;

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

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

o. in their "Medication Guide" intended for distribution to patients to whom Eliquis has been prescribed, Defendants failed to adequately 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 include a warning in the Warning Section of the label of that prothrombin time (PT), INR, or activated partial thromboplastin time (aPTT) or other assay are commercially available to monitor and test anticoagulation to mitigate the risks of bleeding.

q. Failed to include a warning in the Warning Section of the label of that commercially available assays were available to monitor and test Factor Xa activity to mitigate the risks of bleeding.

r. Failed to include a warning that Eliquis should not be used in certain patient populations due to an increased risk of major adverse events.

s. Failed to include a warning that Eliquis should be a last resort in certain patient populations due to an increased risk of major adverse events.

65. If Defendants provided stronger and adequate warning, Plaintiff's prescribing physician would have prescribed a different medication and would have advised Plaintiff to not take Eliquis.

66. Despite life-threatening bleeding findings in a 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.

67. 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 associated 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.

68. 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 in the patient populations who would actually use the drug.

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

70. 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 this medication inadequate.

71. In general, since its approval in 2012, there has been a growing concern amongst physicians regarding the absence of guidance for dealing with the unstoppable bleeds of Eliquis.

72. Numerous other studies published after Eliquis' approval in 2012 confirm the problematic bleeding events associated with Eliquis, and critique the complete lack of ability to stop a bleeding event once one occurs.

73. Despite a ballooning market share and a 400% increase in prescriptions of Eliquis in 2015, Defendants have relayed very little information on how to stop a potentially life-threatening bleeding event to first responders and treating health-care providers.

74. With no readily available reversal strategy, many patients, such as Plaintiff herein, have been substantially injured.

75. Defendants marketing, selling, and distributing a drug with no known mechanism to stop the bleeding once it starts is an unreasonably dangerous design of the drug.

76. Significant questions have also been as to the validity of the ARISTOTLE data and the Eliquis label regarding the twice-a-day dosing strategy. The label, in the Warning and Precaution Section, fails to adequately warn physicians and patients that the amount of Eliquis will accumulate in certain patients exposing them to an increased risk of bleeding and there is a significant intra-and inter patient variability with regard to the drug levels of Eliquis despite the twice-a-day dosing at the 2.5 mg and 5 mg dosing. Studies show that blood levels of Eliquis vary widely from patient to patient with high and low blood levels strongly linked to the likelihood of major bleeding or stroke, respectively. This is because the very nature of any anti-coagulant and its effect is to be "on edge." Too much anti-coagulation will cause excessive bleeding, while too little will not have the needed effect. That is why warfarin always required physicians to monitor the anti-coagulation level of each patient's blood. Further, as patients age or change over time, the needed dosage of warfarin would concurrently change. Eliquis is no different in that the level of Eliquis fluctuates despite the twice-a-day dosing system; thus, a patient on Eliquis could either fall below the amount of drug needed to be within therapeutic range or be exposed to too much of the drug. Thus, Defendants' design is unreasonably dangerous without either a mechanism in place to accurately determine the drug concentration levels in certain patient populations or when faced with a medical emergency.

77. Alternatively, Defendants should have included a warning that Eliquis' drug concentration levels are not stable intra and inter patient is unreasonably dangerous. Because there are no monitoring requirements currently in place, in the hopes of being more convenient, virtually every patient is prescribed Eliquis to be taken twice per day. Therefore, the dosage for virtually all patients is not personalized based on the patient's traits, but instead fits into one of

two "methods" of prescribing. Most A-Fib patients receive 5 mg of Eliquis to be taken twice per day. Certain other patients – those over 80, weighing less than 132 lbs, or who show a certain level of serum creatinine, the dose is 2.5 mg twice a day. Those are the only two methods of dosing for Eliquis. This is in sharp contrast to warfarin, which tailors a specific dosage for every patient, and then monitors that dosage to ensure the correct amount of anti-coagulation is occurring. Without a specifically tailored dose and regular monitoring, it is unclear if the correct and desired amount of anti-coagulation is occurring, leading to more bleeding events or ischemic strokes. In addition, Defendants warning were in adequate to inform physicians of this potential risk.

78. The warning label for Eliquis is inadequate. The original Eliquis label from December 2012 does not include a BLACK BOX warning for irreversible bleeding events, no warnings regarding the inability to measure the drug concentration of Eliquis or the degree of anticoagulation, or that there is no antidote for such a bleeding event.

79. Importantly, warning labels as recently updated as July 2016 still do not include such a BLACK BOX or BOXED warning regarding unstoppable bleeding, inability to monitor either the effects of anticoagulation or the level of drug concentration, and that there is no antidote.

80. In contrast, Warfarin carries a black box warning of bleeding risk.

81. In addition to its failure to adequately and appropriately update its warning labels for the Eliquis product, Defendants have failed to issue a "Dear Doctor" letter that sufficiently outlines the dangers of prescribing and administering Eliquis to a patient.

82. The current warning is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including Plaintiff.

83. Even if the warnings were sufficient, which Plaintiff strongly deny, Eliquis still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug.

84. Eliquis is quite simply dangerous and defective as formulated and the Defendants

should withdraw Eliquis from the market.

85. Specifically, Defendants' product original and updated labeling and prescribing information for Eliquis:

a. failed to 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 effects on the degree of anticoagulation in a patient;

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 that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis and the consequences of that;

f. failed to advise prescribing physicians, such as the Plaintiff's physicians, to instruct patients that there was no agent to reverse the anticoagulant effects of Eliquis and the consequence of that;

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 increased risk of suffering a bleeding event, requiring blood transfusions in those taking Eliquis;

k. 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;

l. 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;

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

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

o. in their "Medication Guide" intended for distribution to patients to whom 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 appropriately warn about the connection between physical trauma, such as head trauma, and the initiation of bleeding events;

q. in their "Medication Guide" intended for distribution to patients to whom 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.

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

s. Failed to warn regarding the need for more comprehensive, more regular medical monitoring to ensure early discovery of potentially serious side effects; and

t. Failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly and inaccurately that two available doses will fit all patients.

u. Failed to warn that certain patients should not take Eliquis due to the increased risk of adverse events, including those who previously had a bleeding event.

v. Failed to warn that certain patients should take Eliquis only as a last resort due to the increased risk of adverse events.

86. Plaintiff's doctor would not have prescribed Eliquis and Plaintiff, who had a medical history of a prior bleed, would not have taken Eliquis had Defendants warned that Eliquis should not have prescribed Eliquis or it should have been prescribed as a last resort given that there was a history of bleeding in Plaintiff's medical history.

87. 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 associated 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.

88. With no readily available reversal strategy, many patients, such as Plaintiff herein, has been substantially injured.

89. Plaintiff's doctors would not have prescribed Eliquis had his or her prescribing doctor received an adequate warning.

90. And Plaintiff's doctors would have utilized a monitoring test had Defendants provided a specific assay designed for Eliquis or instructed for the use of already commercially available assays that could measure the effect of Eliquis, especially in the event of a medical emergency or when emergent surgery is needed.

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

92. 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 this medication inadequate.

93. By reason of the foregoing acts and omissions, Plaintiff has endured and continues to suffer including medical expenses, physical pain and mental anguish, diminished

enjoyment of life, and loss of earnings, among other damages for an amount less than $75,000.00.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS (NEGLIGENCE)

91. Plaintiff repeats, reiterates and realleges 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.

92. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and distribution of Eliquis into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable dangerous side effects.

93. The Eliquis is defective product and its defects are as a result of Defendants' negligence.

94. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and distribution of Eliquis into interstate commerce in that Defendants knew or should have known that using Eliquis created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and shortened life expectancy.

95. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physician(s).

96. The negligence of the Defendants, their agents, servants, and employees, included but was not limited to the following acts and omissions:

(a) Manufacturing, producing, promoting, formulating, creating and designing Eliquis without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and designing Eliquis without adequately testing it;

(c) 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;

(d) Selling Eliquis without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Eliquis;

(f) 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;

(g) Failing to test Eliquis and failing to adequately, sufficiently and properly test Eliquis;

(h) Negligently advertising and recommending the use of Eliquis without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Eliquis was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Eliquis had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(k) Negligently designing Eliquis in a manner which was dangerous to its users;

(l) Negligently producing Eliquis in a manner which was dangerous to its users;

(m) Negligently assembling Eliquis in a manner which was dangerous to its users;

(n) Concealing information from the Plaintiff in knowing that Eliquis was unsafe, dangerous and non-conforming with FDA regulations;

(o) Improperly concealing and misrepresenting information from the Plaintiff, healthcare professionals, and the FDA, concerning the severity of risks and dangers of Eliquis compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(p) Negligently represented that the dosing regimen fit all patients, whereas they knew or should have known that proper dosage depending on individualizing factors in users.

(q) Failing to design a specific assay and /or antidote before sending Eliquis to the FDA for approval;

(r) Failing to include a warning or an instruction that test were available, including a Neoplastin PT, INR, aPTT, dPTT, or other similar test or chromogenic assays available to measure anticoagulation.

(s) Failed to accompany their product with proper and accurate warnings regarding all possible adverse side effects associated with the use of Eliquis;

(t) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and malfunction of Eliquis;

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

(v) Failed to warn Plaintiff 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;

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

(x) Failed to warn Plaintiff, 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 to ensure early discovery of potentially serious side effects;

(y) Failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly that one dosage fit all patients;

(z) Failed to warn that Eliquis should not be used in certain populations;

(aa) Failed to warn that Eliquis should only be used in certain populations as a last resort;

(bb) Were otherwise careless and negligent.

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

98. Defendants negligently compared the safety risk and dangers of Eliquis with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

99. Despite the fact that Defendants knew or should have known that Eliquis caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and sell Eliquis to consumers, including Plaintiff.

100. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

101. Defendants owed a duty to learn about new safety data from many sources, including a new analysis of existing information. Defendants failed, however, to perform a systematic meta-analysis and /or signal investigation combining all available evidence, including

(a) conducting systematic and routine monitoring of the Adverse Event Reporting System or other databases for specific safety concerns;

(b) post-marketing adverse drug experience;

(c) medical literature;

(d) foreign regularity authorities post-marketing surveillance;

(e) new analysis of existing information;

(f) studies, clinical trials or observational studies; and

(g) REMs assessments.

102. Plaintiff did not have the same knowledge as Defendant and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

103. By failing to warn Plaintiff and Plaintiff's prescribing physician(s) of the adverse health risks associated with Eliquis, Defendants breached their duty to Plaintiff of reasonable care and safety.

104. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Eliquis, to health care providers empowered to prescribe and dispense Eliquis to consumers, including Plaintiff. Through both omissions and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Eliquis, which resulted in Plaintiff's physician prescribing Eliquis. If Defendants would not have made these omissions and affirmative misstatements or provided stronger warnings regarding the risks associated with Eliquis, Plaintiff's physician prescribing Eliquis would have altered his prescribing decision.

105. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered.

106. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, bleeding, physical pain and mental anguish, diminished enjoyment of life, medical expenses, and loss of earnings for an amount less than $75,000.00.

107. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged.

SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

108. Plaintiff repeats, reiterates and realleges 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.

109. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Eliquis as hereinabove described that was used by the Plaintiff. That Eliquis was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

110. At those times, Eliquis was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

111. 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 suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Eliquis.

112. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and formulation in that, when it left the hands of the Defendants, manufacturers, and suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

113. The dosages and/or formulation of Eliquis was unreasonably dangerous in design and there are no patients for whom the benefits of Eliquis outweighs the risk.

114. 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 Defendant.

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

116. At the time of the Plaintiff's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended.

117. Defendants failed to exercise reasonable care in the design of Eliquis because as designed, Eliquis was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants also failed to exercise reasonable care in marketing of Eliquis because they failed to warn that Eliquis as designed was capable of causing serious injuries such as those suffered by Plaintiff during foreseeable use.

118. Eliquis was further defective in design due to inadequate post-marketing warnings and instruction because Defendants knew or should have known of the risk and danger of serious bodily harm and or death from the use of Eliquis, but failed to provide an adequate warning to patients and prescribing physicians of the product, knowing the product could cause serious injury and death.

119. Eliquis was further defective in design in that there are safer and more efficacious drug products that did not carry the same risk and dangers that Defendants' Eliquis had.

120. 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.

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

122. Defendant failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Eliquis was a proximate cause of Plaintiff's

injuries.

123. At the time of the Plaintiff's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended.

124. Defendants with this knowledge voluntarily designed its Eliquis in a dangerous condition for use by the public, and in particular the Plaintiff.

125. The foreseeable risks associated with the design and formulation of Eliquis include, but are not limited to, the fact the design or formulation of Eliquis is more dangerous than a reasonably prudent consumer or prescribing physician would expect when used in an intended or reasonably foreseeable manner, and / or did not have the claimed benefits.

126. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

127. Defendants created a product unreasonably dangerous for its normal, intended use.

128. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Eliquis left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

129. Eliquis as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Eliquis was manufactured.

130. 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.

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

132. The defective and unreasonably dangerous design and marketing of Eliquis was a direct, proximate, and producing cause of Plaintiff's injuries and damages.

133. The absence of an adequate warning provided to Plaintiff or his physician caused Plaintiff's injuries.

134. Among other things, Defendants—prior to FDA approval— should have, but failed to design:

a. an Eliquis-specific test so doctors could monitor Eliquis's anticoagulation effect in each patient and could, along with the patient, weigh the risks and determine whether to take Eliquis;

b. design and market an antidote to counteract a major bleeding event; and

c. a label that warns that a bleeding event without a reversal agent or ability to measure the degree of anticoagulation could result in a worse outcome than those anticoagulants with reversal agents or laboratory testing for monitoring.

d. a label the Warns that commercially available assays or tests may mitigate the risk of bleeding in an emergent situation.

135. Defendants, as manufacturers and distributers of Eliquis, 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 significant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with Eliquis was inadequate.

136. 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 Plaintiff's prescribing physicians. The warnings that were given by the Defendant were not accurate, clear, and / or were ambiguous or incomplete.

137. In the Warnings and Precaution Section of the Eliquis label, there is nothing indicating to a physician or patient that there is no ability to monitor the level of the drug in a patient's system and the consequences of the inability to accurately monitor the amount of Eliquis in one's system may be. There is no warning, for example, that the inability to monitor the amount of Eliquis in one's system will delay intervention in the event of a medical emergency. If there was an

ability to monitor the amount of Eliquis in a patient's system, it would help emergency providers in assessing and treating patients who present with life-threatening bleeds.

138. The label, in the Warning and Precaution Section, fails to adequately warn physicians and patients that the amount of Eliquis will accumulate in certain patients exposing them to an increased risk of bleeding.

139. Defendants owed a duty of reasonable care to adequately warn of risks associated with the use of Eliquis to Plaintiff and the general public.

140. Defendants knew or should have known that the warnings provided to Eliquis users regarding the risks associated with its use were incorrect and misleading in the following respects:

a. Eliquis was unaccompanied by proper warnings regarding all possible side effects associated with its use and the comparative severity, incidence, and duration of such adverse effect;

b. Eliquis was defective due to inadequate post-marketing warnings or instructions because Defendants failed to provide adequate warnings to users, consumers, and prescribing physicians even after Defendants knew or should have known of the risk of injury from Eliquis;

c. Eliquis was unaccompanied by proper warnings regarding irreversible bleeding caused by Eliquis and Defendants continued to aggressively promote Eliquis even after it knew or should have known of irreversible bleeding from the drug;

d. Defendants failed to warn that there were other drugs available that did not have the same risks as Eliquis. an Eliquis-specific test so doctors could monitor Eliquis's anticoagulation effect in each patient and could, along with the patient, weigh the risks and determine whether to take Eliquis;

e. design and market an antidote to counteract a major bleeding event; and

f. a label that warns that a bleeding event without a reversal agent or ability to measure the degree of anticoagulation or anticoagulant in one' could result in a worse outcome than those anticoagulants with reversal agents or laboratory testing for monitoring.

141. By failing to warn Plaintiff and Plaintiff's physicians of the adverse health risks

associated with Eliquis, Defendants breached their duty to Plaintiff of reasonable care and safety.

142. 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, consumers, or prescribing physicians of the product, and continued to improperly advertise, market and promote their product, Eliquis.

143. Despite the fact Defendants knew or should have known that Eliquis caused unreasonable and dangerous side effects, they continued to promote and market Eliquis without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

144. Defendants had an obligation to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff, and their intermediary physician regarding the adverse health risks associated with exposure to Eliquis and / or safer or more equally effective alternative drug products. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding these adverse health risks associated with the exposure to Eliquis and /or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

145. Plaintiff's physicians would not have prescribed Eliquis if Defendants provided accurate information, and adequately warned of bleedings risks, adequately warned of irreversibility of anticoagulation, which is life-threatening in the event of a major bleed.

146. Plaintiff's physicians would have used a specific assay for Eliquis if available and would have used currently available assays and laboratory tests when treating Plaintiff's bleed.

147. Defendants had a duty to create a product that was not unreasonably dangerous for its normal intended use.

148. Defendants created a product unreasonably dangerous for its normal intended use.

149. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was manufactured defectively in that Eliquis left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

150. Eliquis as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Eliquis was manufactured.

151. 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.

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

153. Eliquis as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

154. Eliquis as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and inadequate testing.

155. 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.

156. By reason of the foregoing, the Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution and selling of a defective product, Eliquis.

157. Defendants' defective design, manufacturing defect, and inadequate warnings of Eliquis were acts that amount to willful, wanton, and reckless conduct by Defendants.

158. Eliquis, as a result of Defendants' negligence, is a defective product

159. The aforementioned defects in Defendants' drug Eliquis were a substantial factor in causing Plaintiff's injuries. Specifically, Plaintiff's physicians would not have prescribed Eliquis had Defendants provided an adequate warning. Consequently, Plaintiff would have never ingested the Eliquis.

160. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including life-threatening bleeding, as well as other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, shortened life

expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

161. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF EXPRESS WARRANTY)

162. Plaintiff repeats, reiterates and realleges 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.

163. Defendants expressly warranted that Eliquis was safe and well accepted by users.

164. Eliquis does not conform to these express representations because Eliquis is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants.

165. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss and will seek damages for an amount less than $75,000.00.

166. Plaintiff did rely on the express warranties of the Defendants herein.

167. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Eliquis in recommending, prescribing and dispensing Eliquis.

168. The Defendants herein breached the aforesaid express warranties, as their drug Eliquis was defective.

169. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Eliquis was safe and fit for use for the purposes intended, that it was

of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

170. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Eliquis was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

171. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

172. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

173. Plaintiff repeats, reiterates and realleges 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.

174. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Eliquis and have recently acquired the Defendants who have manufactured, compounded, portrayed,

distributed, recommended, merchandized, advertised, promoted and sold Eliquis to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

175. At the time Defendants marketed, sold and distributed Eliquis for use by Plaintiff, Defendants knew of the use for which Eliquis was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

176. The Defendants impliedly represented and warranted to the users of Eliquis and their physicians, healthcare providers, and the FDA that Eliquis was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

177. That said representations and warranties aforementioned were false, misleading and inaccurate in that Eliquis was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

178. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

179. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Eliquis was of merchantable quality and safe and fit for its intended use.

180. Eliquis was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

181. The Defendants herein breached the aforesaid implied warranties, as their drug Eliquis was not fit for its intended purposes and uses.

182. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

183. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

184. Plaintiff repeats, reiterates and realleges 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.

185. The Defendants falsely and fraudulently represented to the medical and healthcare community, Plaintiff's prescribing physician, and to the Plaintiff, and the FDA, and the public in general, that said product, Eliquis, had been tested and was found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

186. Defendants failed to exercise ordinary care in the representation of Eliquis, while involved in its manufacture, sale, testing, quality assurance, quality control, and distribution of said product into interstate commerce, in that Defendants negligently misrepresented Eliquis' high risk of unreasonable, dangerous side effects.

187. Defendants breached their duty in representing Eliquis' serious side effects to the

medical and healthcare community, to the Plaintiff, the FDA and the public in general.

188. Defendants negligently misrepresented to Plaintiff the safety and effectiveness of Eliquis and concealed material information, including adverse information regarding the safety and effectiveness of Eliquis. The misrepresentations and /or material omissions made by or perpetuated by Defendants are as follows:

a. Defendants failed to conduct sufficient testing which, if properly performed, would have shown Eliquis had serious side effects, and warn users of those risks; and/or

b. Include adequate warnings with Eliquis that would alert users to the potential risks and serious side effects;

c. Include warnings about commercially available assays or laboratory tests to assess the effects of Eliquis; and / or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Eliquis.

189. Defendants made the misrepresentations and omissions with the intent that Plaintiff, Plaintiff's physicians, the general consuming public, and health-care providers rely on such information or the absence of such information in the selection of Eliquis.

190. Plaintiff and Plaintiff's physicians justifiably relied on and /or were induced by the misrepresentations and /or active concealment by Defendants and relied upon the absence of safety information, which Defendants suppressed, concealed, or failed to disclose, all to Plaintiff's detriment.

191. That representations made by Defendants were, in fact, false.

192. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

193. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, 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 purchase said product, Eliquis, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

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

195. In reliance upon said representations, the Plaintiff was induced to and did use Eliquis, thereby sustaining severe and permanent personal injuries.

196. Defendants knew and were aware or should have been aware that Eliquis had not been sufficiently tested, was defective in nature, and that it lacked adequate and sufficient warnings.

197. 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 was inherently dangerous in a manner that exceeded any purported, inaccurate, and down-played warnings.

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

199. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe

and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

200. By reason of the foregoing, Plaintiff have suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

201. Plaintiff repeats, reiterates and realleges 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.

202. At all times during the course of dealing between Defendants and Plaintiff and Plaintiff's healthcare providers, and the FDA, Defendants misrepresented the safety of Eliquis for its intended use.

203. Defendants knew or were reckless in not knowing that its representations were false.

204. In representations to Plaintiff and Plaintiff's healthcare providers, and the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Eliquis was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) that the risks of adverse events with Eliquis were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of

DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(c) that the risks of adverse events with Eliquis were not adequately tested and known by Defendants;

(d) that Defendants were aware of dangers in Eliquis, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(e) that Eliquis was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(f) that patients needed to be monitored more regularly than normal while using Eliquis;

(g) that Eliquis was manufactured negligently;

(h) that Eliquis was manufactured defectively;

(i) that Eliquis was manufactured improperly;

(j) that Eliquis was designed negligently;

(k) that Eliquis was designed defectively; and,

(l) that Eliquis was designed improperly.

205. Defendants were under a duty to disclose to Plaintiff and Plaintiff's physicians, hospitals, healthcare providers, and the FDA the defective nature of Eliquis, including but not limited to the heightened risks of life-threatening bleeding.

206. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Eliquis, including the Plaintiff in particular.

207. Defendants' concealment and omissions of material facts concerning the safety of Eliquis was made purposefully, willfully, wantonly, and recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Eliquis, and actions thereon, and to cause them to purchase, prescribe, and dispense Eliquis and use the product.

208. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Eliquis, as set forth herein.

209. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and hospitals reasonably relied on facts revealed which negligently, fraudulently and purposefully did not include facts that were concealed and omitted by Defendants.

210. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages less than $75,000.00, and in some cases, death.

211. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

212. Plaintiff 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.

213. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA, and the public in general that said product, Eliquis, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

214. The representations made by Defendants were, in fact, false.

215. Defendants failed to exercise ordinary care in the representation of Eliquis, while involved in its manufacture, sale, testing, quality assurance, quality control, and distribution of said product into interstate commerce, in that Defendants negligently misrepresented Eliquis' high risk of unreasonable, dangerous side effects.

216. Defendants negligently misrepresented to Plaintiff the safety and effectiveness of Eliquis and concealed material information, including adverse information regarding the safety and effectiveness of Eliquis. The misrepresentations and /or material omissions made by or perpetuated by Defendants are as follows:

a. Defendants failed to conduct sufficient testing which, if properly performed, would have shown Eliquis had serious side effects, and warn users of those risks; and/or

b. Include adequate warnings with Eliquis that would alert users to the potential risks and serious side effects;

c. Include warnings about commercially available assays or laboratory tests to assess the effects of Eliquis; and / or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Eliquis.

217. Defendants made the misrepresentations and omissions with the intent that Plaintiff, Plaintiff's physicians, the general consuming public, and health-care providers rely on such information or the absence of such information in the selection of Eliquis.

218. Plaintiff and Plaintiff's physicians justifiably relied on and /or were induced by the misrepresentations and /or active concealment by Defendants and relied upon the absence of safety information, which Defendants suppressed, concealed, or failed to disclose, all to Plaintiff's detriment.

219. Defendants breached their duty in representing Eliquis' serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

220. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

221. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD)

222. Plaintiff repeats, reiterates and realleges 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.

223. Defendants conducted research, or lack thereof, and used Eliquis as part of their research.

224. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and the FDA that Eliquis was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

225. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and the FDA, including Plaintiff.

226. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and the FDA.

227. The information distributed to the public, the FDA, and the Plaintiff, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and omissions.

228. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Eliquis was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

229. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Eliquis carried the same risks, hazards, and dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

230. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included false representations that Eliquis was not injurious to the health and safety of its intended users.

231. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Eliquis was as potentially injurious to the health and safety of its intended users, as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

232. These representations were all false and misleading.

233. Upon information and belief, Defendants intentionally supposed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Eliquis was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and was not as safe as other means of treatment for reducing the risk of stroke and systemic

embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

234. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Eliquis, specifically but not limited to Eliquis not having dangerous and serious health and safety concerns.

235. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Eliquis, specifically but not limited to Eliquis being a safe means of reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

236. It was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and the Plaintiff, to falsely ensure the quality and fitness for use of Eliquis and induce the public and the Plaintiff to purchase, request, dispense, prescribe, recommend, and continue to use Eliquis.

237. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Plaintiff that Eliquis was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

238. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Plaintiff that Eliquis was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

239. Defendants made claims and representations in their documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Eliquis did not present serious health and safety risks.

240. Defendants made claims and representations in their documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Eliquis did not present health and safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

241. These representations and others made by Defendants were false when made, and were made with a pretense of actual knowledge when knowledge did not actually exist, and were made recklessly and without regard to the actual facts.

242. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's healthcare professionals

and the FDA, and were made in order to induce the Plaintiff and Plaintiff's healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and prescribe Eliquis.

243. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and safety concerns of Eliquis to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

244. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Eliquis by concealing and suppressing material facts regarding the dangerous and serious health and safety concerns of Eliquis.

245. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's healthcare professionals into a sense of security so that Plaintiff would rely on the representations made by Defendants, and purchase, use and rely on Eliquis and that Plaintiff's healthcare providers would dispense, prescribe, and recommend the same.

246. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's healthcare professionals would rely upon the information being disseminated.

247. Defendants utilized direct to consumer advertising to market, promote, and advise Eliquis.

248. Defendants misrepresented the safety of Eliquis, represented that Eliquis was safe for use, and concealed warnings of the known or knowable risks and side effects of Eliquis. 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 withheld information and data that without the reversal agent, death could result;

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.

249. When Defendants made these representations, they knew that such representations were false. Defendants made the representations with the intent to defraud and deceive Plaintiff, consumers, and the public in general, and with the intent to induce them to use Eliquis in the manner alleged in this Complaint.

250. Plaintiff took the actions alleged in this Complaint, while ignorant of the falsity of Defendants' representations and reasonably believed them to be true. In reliance upon such representations, Plaintiff were induced to, and did, use Eliquis as alleged in this Complaint. If

Plaintiff had known the actual facts, Plaintiff would not have used Eliquis, and his reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

251. The Plaintiff and Plaintiff's healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Eliquis.

252. The Plaintiff and Plaintiff's healthcare providers did not know the truth with regard to the dangerous and serious health and safety concerns of Eliquis.

253. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and safety concerns, and the false representations of the Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

254. Had Plaintiff known the true facts with respect to the dangerous and serious health and safety concerns of Eliquis, Plaintiff and Plaintiff's prescribing physicians would not have purchased, used, prescribed, and relied on Defendants' drug Eliquis.

255. The Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly and purposefully on the Plaintiff.

256. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental

anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

257. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF CONSUMER PROTECTION LAWS)

258. Plaintiff repeats, reiterates, and realleges 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.

259. Defendants have a statutory duty to refrain from making false or fraudulent representations and from engaging in deceptive acts or practices in the sale and promotion of Eliquis pursuant to the applicable state's consumer protection laws.

260. Defendants engaged in unfair, deceptive, false and fraudulent acts and practices in violation of the applicable state's consumer protection law through its false and misleading promotion of Eliquis designed to induce Plaintiff to purchase and use Eliquis and Plaintiff's physicians to prescribe it.

261. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

(a) Publishing instructions and product material containing inaccurate and incomplete factual information.

(b) Misrepresenting the nature, quality, and characteristics about the product; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

262. Specifically, at all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements, by engaging in the following acts and practices with intent to induce members of the public to purchase and use Eliquis:

a) representing that Eliquis is safe, fit and effective for human consumption, and safe and effective for its indicated uses and concealing from Plaintiff, their physicians, and the general public that Eliquis has an increased propensity to cause injuries to users;

b) engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Eliquis is safe, fit and effective for human consumption, safe and effective for its indicated uses, even though Defendants knew these representations to be false, and even though Defendants had no reasonable ground to believe them to be true;

c) engaging in a practice, undertaking unlawful, unfair or fraudulent acts by refraining from taking any action that would provide prescribing physicians with appropriate information and protect patients who ingest or use their drugs, including Plaintiff, such as failing to engaging in proper pharmacovigilance, signal detection and follow up, review of the literature, regulatory review, updating labels and taking appropriate action to disseminate to prescribing physicians and healthcare providers appropriate and permitted product information and labels concerning safety issues and safe prescribing practices for their products.

d) Over-promotion of Eliquis, including but not limited to the over promotion of their safety and efficacy;

e) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and misunderstanding.

263. Defendants misrepresented the alleged benefits of Eliquis, failed to disclose material information concerning known side effects of Eliquis, misrepresented the quality of Eliquis, and otherwise engaged in fraudulent and deceptive conduct which induced Plaintiff to purchase and use Eliquis and Plaintiff's physicians to prescribe it.

264. Defendants uniformly communicated the purported benefits of Eliquis while failing to disclose the serious and dangerous side effects related to the use of Eliquis, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical

community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.

265. Defendants' conduct in connection with Eliquis was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Eliquis.

266. Defendants' conduct as described above was a material cause of Plaintiff's decision to purchase Eliquis and Plaintiff's physicians to prescribe it.

267. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of applicable state law the Plaintiff suffered damages, including personal injuries, economic damages, and non-economic damages.

268. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages for an amount less than $75,000.00.

269. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

TOLLING STATUTE OF LIMITATIONS

270. Plaintiff hereby incorporates by reference all other paragraphs in this Complaint as if set forth fully herein.

271. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Eliquis caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of facts indicating to a reasonable person that Plaintiff were the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

272. Furthermore, the running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and consumers the true risks associated with Eliquis.

273. As a result of Defendants' actions, Plaintiff and consumers were unaware, and could not reasonably know or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

274. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety Eliquis. Defendants were under a duty to disclose the true character, quality and nature of Eliquis because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or their health facilities, yet they failed to disclose the information to the public.

275. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purposes of marketing and promoting a profitable product, notwithstanding the known or reasonably knowable risks. Plaintiff, consumers, and medical professionals could

not have afforded to and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and they were forced to rely on Defendants' representations.

PRAYER

WHEREFORE, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiff for the injuries Plaintiff has and will suffer. Plaintiff further demands payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiff further demands payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

Respectfully Submitted,

JACOBS & CRUMPLAR, P.A.

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Counsel for Plaintiff

Dated: January 3, 2018