EFiled: Feb 02 2017 02:38PM EST
Transaction ID 60154371
Case No. N17C-02-024 AML

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

CARMEN FLORES Plaintiff, -against- BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC., Defendants.	:	C.A. NO.: **JURY TRIAL DEMANDED**

COMES NOW Plaintiff, CARMEN FLORES, who by and through the undersigned counsel hereby submits this Complaint against Bristol-Myers Squibb Company and Pfizer Inc., for compensatory and punitive damages, and such other relief deemed just and proper arising from the injuries of CARMEN FLORES as a result of her exposure to the prescription drug ELIQUIS®. In support of this Complaint, Plaintiffs allege the following:

COMPLAINT

COMMON ALLEGATIONS

Plaintiff, at all times relevant hereto, was a citizen and resident of the State of California, who suffered personal injuries as a result of her use of Eliquis.

INTRODUCTION

1. This action involves claims of personal injury, economic damages, punitive damages, and other claims of damage arising from injuries sustained by the Plaintiff, CARMEN FLORES, as a direct and proximate result of both the defective nature of defendants BRISTOL-

MYERS SQUIBB COMPANY and PFIZER INC. pharmaceutical product, Eliquis, generic name apixaban.

PARTIES

2. At all times hereinafter mentioned the Plaintiff, CARMEN FLORES (herein referred to as "Plaintiff"), was a citizen and resident of the State of California, County of Los Angeles.

3. Upon information and belief, at all times hereinafter mentioned, defendant, BRISTOL-MYERS SQUIBB COMPANY ("BMS"), was and is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 345 Park Avenue, New York, New York 10154. Its registered agent for service of process is: c/o CT Corporation 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.

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

5. 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.

6. 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.

7. Upon information and belief, at all times hereinafter mentioned, defendant, PFIZER INC. ("Pfizer"), was and is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, New

York 10017. Its registered agent for service of process is: c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

8. 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."

BACKGROUND

9. Plaintiff, CARMEN FLORES, was prescribed Eliquis, also known as apixaban, because of a diagnosis of atrial fibrillation. On or about February 2, 2015, Plaintiff CARMEN FLORES suffered severe physical, economic, and emotional injuries as a result of Eliquis including, but not limited to, Plaintiff suffering from ischemic stroke.

10. Specifically, plaintiff suffered a severe gastrointestinal bleeding event, which required intermittent hospitalization and treatment.

11. As a direct and proximate result of Defendants' conduct, Plaintiff suffered and incurred harm including severe pain and suffered personal injuries and incurred damages which include severe pain and suffering, medical expenses and other economic and noneconomic damages.

12. 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.

13. In written information about the safety and risks of Eliquis, Defendants negligently and fraudulently represented to the medical and healthcare community, including

Plaintiff's prescribing doctor, the Food and Drug Administration (hereinafter referred to as the "FDA") , to Plaintiff and the public in general, that Eliquis had been tested and was found to be safe and effective for its indicated uses. Defendants concealed their knowledge of Eliquis' defects, from Plaintiff, the FDA, the public in general and the medical community, including Plaintiff's prescribing doctor.

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

15. As a direct and proximate result of Defendants' conduct, Spousal Plaintiff has suffered and incurred damages, including medical expenses; account, and other fees and cost of administration; and other economic and non-economic damages (including pain, and suffering), flowing from the injury of Plaintiff CARMEN FLORES.

FACTUAL ALLEGATIONS APPLICABLE TO ALL COUNTS

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

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

multiple clotting factors to help the blood clot.

18. Coumadin can be carefully monitored and dose-adjusted by way of regular, routine monitoring of the prothrombin time ("PT") and International Normalization Ratio ("INR"). Eliquis' anticoagulation effect, in contrast, cannot be monitored at all. Additionally, unlike Eliquis, which has no publicly known antidote, the anticoagulation effects of Coumadin are reversible with the administration of vitamin K and/or the administration of coagulation factors such as fresh frozen plasma.

19. All anticoagulants have a risk of bleeding. Without an antidote, a bleed can quickly become a life-threatening situation. If a patient presents to the emergency room with a bleed on warfarin, doctors have a variety of options to choose from depending on how quickly they need to reverse anticoagulation. Because warfarin is a vitamin K antagonist, a patient on warfarin presenting with bleeding can have the anticoagulation effects completely reversed within a very short amount of time by administering vitamin K.

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

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

develop an alternative to warfarin.

22. The first novel oral anticoagulant approved in the United States was Pradaxa (dabigatran) in 2010, followed by Xarelto (rivaroxaban) in 2011, Eliquis (apixaban) in 2012, and most recently, Savaya (edoxaban) in 2015. Defendants received FDA approval to market Eliquis in 2012 (NDA 202155).

23. Overall, dispensed outpatient prescriptions for NOACs increased 6.8% to 11.1 million in the fourth quarter of 2015, compared to 2014 Q1. By the fourth quarter of 2015, the four novel anticoagulants had captured 34% of the market, leaving 66% to warfarin. 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 11.8% of dispensed outpatient prescriptions. For Eliquis, this 11.8% market share represents a 446.2% increase.

24. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Eliquis as a "new" or "novel" oral anticoagulant, also known as a Factor Xa inhibitor. Factor Xa is another factor on the coagulation cascade and forms the thrombin, which is required for blood to clot. By inhibiting Factor Xa, Eliquis prevents thrombin from forming, which prevents blood from clotting.

25. Eliquis has two dosages—2.5 mg and 5 mg—approved by the FDA to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. The FDA, in March 2014, expanded the indicated use for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients who have undergone hip or knee replacement. And in August 2014, the FDA label added that Eliqus is indicated for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. Among

the uses for which Defendants obtained permission to market Eliquis was in the treatment of atrial fibrillation. Approval of Eliquis was based in large part on clinical trials known as ARISTOTLE.

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

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

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

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

30. The label fails to disclose other, post-approval studies which criticize the results of ARISTOTLE study, including the findings regarding frequency and severity of bleeds on Eliquis.

31. Instead of admitting the major errors and frauds involved in the ARISTOTLE study, Defendants misleadingly stated publicly that they were submitting "additional data" to the FDA, and to this date have never publicly acknowledged the missing and incorrect data submitted 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.

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

33. Critically, there is no antidote to Eliquis, unlike warfarin. Therefore, in the

event of hemorrhagic complications, there is no available or validated reversal agent or antidote, as there is for Coumadin.

34. Defendants now market Eliquis as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. Defendants emphasize the alleged benefits of treatment with Eliquis over warfarin, in that Eliquis does not require periodic monitoring with blood tests, Eliquis did not limit a patient's diet, and Eliquis has a set dose that fits all patients. Studies from 2014 and beyond have called into question all of these perceived advantages.

35. The U.S. label approved when the drug was first marketed in the U.S. and at the time Plaintiff was using in 2014 it did not contain an adequate warning regarding the lack of antidote, and the significance of that problem for patients who began to bleed.

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

37. In the course of these direct-to-consumer advertisements, Defendants over promoted Eliquis as a "one-size-fits all dosage," overstated the efficacy of Eliquis with respect to preventing stroke and systemic embolism, overstated and misrepresented fact that Eliquis has less major bleeding and stroke risk 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.

38. In 2015 and 2016, Defendants aired several direct to consumer television

advertisements, including, but not limited to, the "Bringing my Best,"[1] "Fisherman,"[2] and "Go for My Best"[3] spots, all of which portray Eliquis as the "best" treatment for Afib and importantly, a better and *safer* alternative to Warfarin. 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.

39. These ads overstated that Eliquis has less major bleeding risk and less stroke risk than Warfarin, 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.

40. 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.

41. In essence, the Defendants created a new drug, Eliquis, which is not better than warfarin from a safety perspective, and marketed it as a superior safety choice that required no blood test monitoring. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendants, but ignores patient safety.

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

[1] https://www.ispot.tv/ad/ABoE/eliquis-bringing-my-best

[2] https://www.ispot.tv/ad/AMeG/eliquis-fisherman

[3] https://www.ispot.tv/ad/AJaT/eliquis-go-for-my-best

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

44. 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.

POST-APPROVAL DATA

45. After the FDA approval of Eliquis, Defendants became aware of many reports of serious hemorrhaging in users of its drugs, both as reported to the FDA and to them directly. Yet Defendants have not fully disclosed to the medical profession or patients which the incidence of such adverse reactions are.

46. Indeed, in its September 25, 2015 QuarterWatch publication (which covers data from Quarters 3 and 4 of 2014), the Institute for Safe Medication Practices ("ISMP") noted that

Eliquis, when used in conjunction with typical platelet inhibitors [aspirin, NSAIDs, and SSRIs, among others], show an increased risk of bleeding events compared to the Defendants' prior clinical data (ARISTOTLE). "In the adverse event data, we found that concomitant therapy with platelet inhibitors while taking anticoagulants increased the odds of a hemorrhage event by threefold (OR 3.01 $p < 0.01$). The increased risk was found across all three of the newer anticoagulants and warfarin."[4]

47. Whether this newly available, post-approval information was submitted to the FDA is unknown. This three-fold increased risk factor for bleeding when Eliquis is used in conjunction with platelet inhibitor therapy is higher than what is indicated in the Eliquis label (See Eliquis Label, Sec. 7.3: Drug Interaction)(noting that data on combination apixaban and platelet inhibitor therapy was limited, and indicating an increased risk of bleeding from 1.8% to 3.4%, or less than a two fold increase).

48. Importantly, the ISMP further indicated:

> The prescribing information for all three drugs contains no guidance on the concomitant use of antiplatelet agents other than a warning that an increased risk of bleeding was observed. The unsolved problem of combination therapy was further illustrated by the clinical trials in which lower doses of the three novel anticoagulants were tested in high-risk heart patients with Acute Coronary Syndrome (ACS) but only when added to the established treatments using platelet inhibitors. **The apixaban trial was stopped because of excess bleeding and no identifiable benefits**.[5]

49. This post-approval signal data, culled from real world usage rather than the controlled patient population of the ARISTOTLE study, shows a higher than indicated risk of a bleeding event with or without combination therapy.

50. Additionally, the ISMP detailed that, for 2014, Eliquis produced 1,014 adverse

[4] *See* https://www.ismp.org/QuarterWatch/pdfs/2014Q4.pdf at 12.
[5] *Id.* (emphasis added).

event reports.[6] 108 of those were a death outcome (10.7%), 224 thrombotic events (22.1%) and 492 hemorrhage events (48.5%). Though the volume of reports for Eliquis (apixaban) in 2014 was lower compared to other NOACs because of the lower volume of prescriptions, the ISMP noted that "the differences with rivaroxaban [Xarelto] in percentage of deaths and total hemorrhage cases were small." This is critical because real-world signal data from Xarelto was also found to have a much high incidence of adverse events than reported in the clinical studies.[7]

51. Subsequently, in 2015, Eliquis produced more than 6,000 adverse event reports. Again, the dominant report was hemorrhaging, with gastrointestinal hemorrhaging a close second.

52. Nor is the ISMP the only study to dispute the findings of the ARISTOTLE trial data. In May 2016, post-approval, the British Medical Journal ("the BMJ") published a meta-analysis on the Comparative effectiveness and safety of non-vitamin K antagonist oral anticoagulants and warfarin in patients with atrial fibrillation.[8] It was found that when limited to stroke, "NOACs were not significantly different from warfarin" in terms of the increased risk of a stroke occurring.[9] This is in direct contradiction to the ARISTOTLE data and Defendants' promotional materials to consumers and physicians.

53. Ultimately, these post-approval statistics indicated a higher than expected signal of bleeding events for Eliquis in comparison to the pre-approval clinical trials, including higher than reported death and hemorrhage events.

---

[6] *Id.*

[7] Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" http://www.reuters.com/article/2013/09/08/us-bayer-xareltoidUSBRE9870AH20130908

[8] http://www.bmj.com/content/353/bmj.i3189

[9] *Id.* ("The hazard ratios for dabigatran and apixaban (2.8% and 4.9% annually, respectively) were non-significant compared with warfarin.")

54. The FDA itself is conducting a study only recently begun in November 2016, involving investigation into the strong adverse event signal connection between Eliquis and vasculitis.[10]

55. Despite the clear signals generated by this side effect data collected after Eliquis' 2012 FDA approval, Defendants failed to either alert the public and the scientific community or perform further investigation into the safety of Eliquis.

POST-APPROVAL CLINICAL CONCERNS REGARDING ELIQUIS AND ITS LABELING

56. Since its release in 2012, three primary clinical questions regarding Eliquis and its clinical data have emerged: (1) is the "one size fits all" method of prescribing viable, (2) the total silence and lack of guidance on the label regarding what steps to take if a patient suffers a bleeding event, and (3) what to do if an Eliquis patient needs emergent surgery.

a. Stopping Bleeding Events.

57. 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. A 2014 study published in the Journal of Thrombosis and Thrombolysis noted that "[a] concern among clinicians is a *virtual absence of guidance* from clinical trials for reversing the anticoagulant effects of these drugs in clinical settings such as life-threatening bleeding or a need for emergent procedures that carry bleeding risk."[11]

58. Numerous other studies published after Eliquis' approval in 2012 confirm the

---

[10] *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm534355.htm

[11] Jackson, L.R. & Becker, R.C. J Thromb Thrombolysis (2014), *Novel oral anticoagulants: pharmacology, coagulation measures, and considerations for reversal*, 37: 380. doi:10.1007/s11239-013-0958-0

problematic bleeding events associated with Eliquis, [12] and critique the complete lack of guidance on how to potentially stop a bleeding event once one occurs.[13]

59. Despite a ballooning market share and a 400% increase in prescriptions of Eliquis in 2015, Defendants apparently cannot be bothered to detail any information how to stop a potentially life threatening bleeding event in their clinical information. Only in its recent July 2016 label update have Defendants even begun to indicate in the label the possible avenues for controlling a bleed once one begins, information that apparently has been known since 2013. That label change was made only after Plaintiff was already taking and was injured by Eliquis. And even then, there is no guarantee that these treatments will stop a bleeding event once one begins.

60. There is even data available as to what *will not* assist in stopping a bleeding event. Another 2014 study from a thrombolic medical journal noted that "No antidote exists for apixaban and given its high plasma protein binding, hemodialysis will not remove significant amount of the drug."[14] This is opposed to pradaxa, which is affected by hemodialysis, meaning the plasma level of the drug can be reduced when dialysis occurs. For Eliquis, that is not so. In fact, the original label in 2012 makes no mention of hemodialysis at all. The only commentary in the current label is that Eliquis levels are not affected by hemodialysis.

b. "One size fits all" Dosing Concerns and related Safety Profile.

61. Questions have also arisen as to the validity of the ARISTOTLE data and the

[12] See https://thrombosisjournal.biomedcentral.com/articles/10.1186/1477-9560-11-27

[13] *See* Wang X, Tirucherai G, Pannacciulli , Wang J, Elsrougy A, Teslenko V, Chang M, Zhang D, Frost C: Effect of activated charcoal on the pharmacokinetics of apixaban in healthy subjects [abstract]. *Clinical Pharmacol Ther* 2012, 91(Suppl 1):s41.

[14] *See* Jackson LR, 2nd, Becker RC. Novel oral anticoagulants: pharmacology, coagulation measures, and considerations for reversal. *J Thromb Thrombolysis* 2014;37:380-91.

Eliquis label as to the "one size fits all" dosing strategy. In the context of Daiichi's NOAC Savaysa, the FDA recently suggested that more tailored dosing would be beneficial to that drug, as well as all NOACs, including Eliquis. In a broader context, a 2015 study in the annals of hematology suggested that tailoring of dosage for each NOAC would be beneficial.[15]

62. More critically, in February 2016, the British Medical Journal reported that both the European Medicines Agency ("EMA") and the FDA held meetings at the end of 2015 in order to discuss the need to measure blood levels (e.g. regularly monitor) of patients on NOACs and adjust the dose accordingly to maximize benefit and minimize harm to the patient.[16] Of course, such a change in therapy, although much safer, would negate one of the primary advantages of Eliquis touted by Defendants – that no regular monitoring is required.

63. The BMJ further reported:

> "A presentation to EMA last year by Robert Temple, deputy director for clinical science at the FDA's Center for Drug Evaluation and Research, suggests that the FDA believes there is a scientific argument for measuring the blood levels of these drugs and adjusting the dose. "Being too low leads to a stroke, a very bad outcome, and being too high leads to major bleeds, also bad, so that early optimization [of the dose] seems worthwhile[.]"[17]

64. In sum, changing the method of monitoring to tailor the dosage of Eliquis seems to be a much safer alternative, and even the FDA believes so. But whether signal data regarding the above has been sent from Defendants to the FDA is unknown.

c. Surgery and Lack of Warnings or Data.

65. For a patient undergoing a needed or elective surgery, there is no guidance from defendants on when to stop using Eliquis in advance of the surgery. Some studies have

[15] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4742513/

[16] *See* http://www.bmj.com/bmj/section-pdf/914027?path=/bmj/352/8043/This_Week.full.pdf at 181.

[17] *Id.*

suggested discontinuance of other NOACs 24 hours before a surgery, if possible.

66. Studies specific to Eliquis, have indicated that "a 'safe' residual drug level of apixaban for surgery is presently unknown, and no test has been correlated with bleeding risk. As such, there is currently no known threshold at which apixaban patients' bleeding risk are able to be comparable to non-apixaban treated patients."[18]

67. Thus, it is unclear when a patient may no longer be exposed to the higher risk of an Eliquis bleeding event, even after discontinuing using Eliquis. Thus, a patient who needs surgery may be exposed to a higher than indicated risk if bleeding occurs during the surgery. Again, this is newly available information and it is unknown if it has been disclosed to the FDA. But such information is not indicated in the label.

d. Miscellaneous Signal data and Failure to Warn.

68. Nor is any warning given that indicates that a patient using eliquis who suffers a head injury may suffer an unstoppable, and potentially fatal, internal bleeding event. The only discussion of trauma is in the "patient medication guide," not officially part of the label, and certainly not a warning. The only mention of a head trauma is to say to call your physician immediately if a head trauma is suffered. No mention of an unstoppable bleed relating to a head injury is mentioned

69. Peer literature on this issue relating to Warfarin suggested that head trauma for a patient on Warfarin is not a concern once a CT-Scan is conducted and found to be clear. But for NOACs like Eliquis, where there is no method to measure the amount of anti-coagulation going on in a patient's system, there is believed to be a greater risk of a bleeding event occurring in the head even after a CT-Scan.

[18] *See* https://thrombosisjournal.biomedcentral.com/articles/10.1186/1477-9560-11-27

70. From all of this, it seems that 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, or that there is no antidote for such a bleeding event.[19]

71. Importantly, warning labels as recently updated as July 2016 still do not include such a BLACK BOX or BOXED warning regarding unstoppable bleeding.

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

73. 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.

74. 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.

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

76. Eliquis is quite simply dangerous and defective as formulated and the Defendants should withdraw Eliquis from the market.

77. Therefore, Defendants' original and updated product labeling and prescribing information for Eliquis:

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

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

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

[19] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202155s000lbl.pdf

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

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

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

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

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

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

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

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

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

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

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

o. failed to include a "BOLDED WARNNG" about serious bleeding events associates with Eliquis;

p. Failed to appropriately warn about the connection between physical injuries, 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 the symptoms or severity of side effects;

s. failed to warn regarding the need for more comprehensive, more regular medical monitoring to ensure early discovery and 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 one dosage fit all patients.

u. Failed to provide guidance on the concomitant use of antiplatelet agents, other than a limited interaction statement indicating that an increased risk of bleeding was observed during trials.[20]

78. In 2015, JAMA published a report critiquing the ARISTOTLE study and Defendants' promotions and claims of the reduced mortality benefit of Eliquis when opposed to Warfarin. Specifically, JAMA noted that "If one were to exclude the data from the patients at that site [the China site location that was the subject of the controversy detailed above], the claim of a statistically significant mortality benefit disappears."[21] Thus, Defendants' reliance

[20] The unsolved problem of combination therapy was further illustrated by the clinical trials in which lower doses of the three novel anticoagulants were tested in high-risk heart patients with Acute Coronary Syndrome (ACS) but only when added to the established treatments using platelet inhibitors. The Eliquis (apixaban) trial reviewing combination therapy with platelet inhibitors was stopped because of excess bleeding and no identifiable benefits. *See* https://www.ismp.org/QuarterWatch/pdfs/2014Q4.pdf at 12.

[21] Seife C. (2015). Research misconduct identified by the US Food and Drug Administration: out of sight, out of mind, out of the peer-reviewed literature. JAMA Intern Med 175: 569-70 *available at* http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.692.3512&rep=rep1&type=pdf.

on the ARISTOTLE study remains flawed.

79. Since 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.

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

81. An antidote for Eliquis bleeding events, not developed by defendants, was recently rejected by the FDA during phase III trials. No mention of this antidote is made. Defendants provided funding for the research and development of Portola Pharmaceuticals' AndexXa antidote to Eliquis bleeding.[22]

82. The FDA granted accelerated review of AndexXa.

83. However, in August 2016, the FDA rejected AndexXa's application for approval based on questions associated with AndexXa's manufacturing, and the need for additional review of various documents submitted by Portola.

84. It is unknown if AndexXa or any Eliquis antidote will ever be available.

85. 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.

86. By reason of the foregoing acts and omissions, Plaintiff has endured and continues to suffer emotional and mental anguish, loss of support, loss of services, medical and

[22] http://www.fool.com/investing/2016/08/18/is-it-game-over-after-portolas-fda-rejection.aspx

funeral expenses, and other economic and non-economic damages stemming from the injury of the Plaintiff, as a result of the actions and inactions of theDefendants.

FIRST CAUSE OF ACTION
MANUFACTURING DEFECT

87. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense possible, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

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

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

90. The Defendants drug Eliquis was defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale, and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products

differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

91. The Eliquis in question was delivered to Plaintiff in a defective and flawed manner.

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

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

94. At those times, Eliquis was in an unsafe, defective, and inherently dangerous condition, which was unreasonably dangerous to users for its intended or reasonably foreseeable use, and in particular, the Plaintiff herein.

95. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

SECOND CAUSE OF ACTION
FAILURE TO WARN

96. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies

to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law. Defendants are strictly liable for Plaintiff's injuries in the following ways in which they failed to adequately warn of the known dangers of Eliquis:

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

b. Failed to warn that it is believed that a more tailored dosing and blood test monitoring of Eliquis would increase safety and efficacy while reducing the risk of bleeding, even after post-approval information indicated otherwise;

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

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

e. failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis, because even a blood test cannot determine the extent of anticoagulation occurring in a particular patient, ;

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

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

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

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

j. 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;

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

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

n. 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;

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

p. failed to include a "BOLDED WARNNG" about serious bleeding events associates with Eliquis;

q. Failed to appropriately warn about the connection between physical injuries, such as head trauma, and the connection between that trauma and the initiation of a serious, and potentially fatal, bleeding event;

r. 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;

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

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

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

v. Failed to provide guidance on the concomitant use of antiplatelet agents, other than a limited interaction statement indicating that an increased risk of bleeding was observed during trials.[23]

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

x. Failed to indicate that current, post-FDA approval signal data shows a much high risk for a bleeding event to occur than indicated in clinical studies;

y. Failed to indicate that current, post-FDA approval signal data shows that Eliquis may not be safer than Warfarin in regards to reducing risk of stroke;

z. failure to have tests available to determine and demonstrate therapeutic range;

aa. Failure to advise testing for therapeutic range;

bb. Failure to provide a therapeutic range; and

cc. Failure to recommend testing and/or monitoring by providers for therapeutic range, even after post-approval information indicated such monitoring should occur;.

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

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

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

[23] The unsolved problem of combination therapy was further illustrated by the clinical trials in which lower doses of the three novel anticoagulants were tested in high-risk heart patients with Acute Coronary Syndrome (ACS) but only when added to the established treatments using platelet inhibitors. The Eliquis (apixaban) trial reviewing combination therapy with platelet inhibitors was stopped because of excess bleeding and no identifiable benefits.

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

hh. Failed to indicate that the reversal agent's application has been rejected;

ii. Defendants failed to warn of the fraud and irregularities which occurred during the testing of Eliquis during the ARISTOTLE drug trials, and how such irregularities makes Defendants' data and claims unreliable, even after post-approval information studies contradicted ARISTOTLE.

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

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

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

100. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries as well as physical pain and mental anguish, and diminished enjoyment of life, and financial expenses for hospitalization and medical care.

101. Defendants' conduct, as described above, was extreme and outrageous. Defendant's risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public regarding the true risks of bleeding in different population. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

102. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

THIRD CAUSE OF ACTION
PRODUCT LIABILITY- DESIGN DEFECT

103. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, pharmaceuticals, including Eliquis, for the sale to, and use by, members of the general public and specifically to Plaintiff. The Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants reached Plaintiff without substantial change and was ingested as directed.

104. The Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was in an unreasonably and inherently dangerous, defective and unsafe condition, which was dangerous to others when it entered into the stream of commerce and was used by Plaintiff.

105. The Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers and/or suppliers,

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

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

107. At all times relevant hereto, the Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was, and still is, defective, unsafe and inherently dangerous and Defendants knew or should have known that Eliquis was, and still is, defective, unsafe and inherently dangerous, especially when used in the form and manner provided, directed, marketed and advertised by the Defendants.

108. Defendants, as manufacturers and distributors of pharmaceutical drugs, including 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 relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Eliquis were inadequate.

109. Defendants had and continue to have a duty to design and manufacture a product that was not unreasonable dangerous for its normal, usual and intended use.

110. Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed an unreasonably dangerous and defective prescription drug, Eliquis, which created an unreasonable risk to the health of consumers and to the Plaintiff, specifically; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

111. The Eliquis designed, manufactured, researched, tested, advertised, promoted,

marketed, labeled, sold, and distributed by the Defendants reached their intended users in the same defective and unreasonably dangerous condition in which it was manufactured.

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

113. Defendants had and continue to have a duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Eliquis, as it became or could have become available to Defendants.

114. Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed an unreasonably dangerous and defective prescription drug, Eliquis, to health care providers empowered to prescribe and dispense Eliquis to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data.

115. As detailed above, through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Eliquis, which resulted in injury to Plaintiff.

116. As noted above, Despite the fact that Defendants knew or should have known that Eliquis caused unreasonable and dangerous side effects, they continued to promote, market, label, advertise, distribute and sell Eliquis without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Eliquis.

117. The Eliquis designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by the Defendants was defective due to inadequate

postmarket surveillance and/or warnings because after Defendants knew or should have known of the risks of serious side effects, the failed to provide adequate warnings to users and/or consumers of the product and continued to promote, market, advertise, distribute and sell Eliquis.

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

119. Defendants' defective design, manufacture, research, testing, advertising, promoting, marketing, labeling, sale, and distribution of Eliquis, as set forth herein, was done willfully, intentionally and with reckless disregard to the life and safety of Plaintiff and the general public.

A. <u>Design Defect</u>

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

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

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

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

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

d. Eliquis was insufficiently tested;

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

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

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

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

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

124. Specifically, Eliquis was more likely to cause serious bleeding that may be irreversible, permanently disabling, and life-threatening more so than other anticoagulants as to patients in certain patient populations, including those with renal compromise, of a certain age and of certain weight. Additionally, Eliquis was designed with no reversal agent, so that in the event of a hemorrhagic bleed, there would be no method to reverse the bleeding, thus

causing a potentially fatal bleeding episode. At all times herein mentioned, Eliquis was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

125. 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.

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

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

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

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

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

otherwise.

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

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

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

134. As a direct and proximate result of the use of Eliquis, Mrs. Matrazzo suffered serious physical injury (and death), harm, damages and economic loss, and Plaintiff will continue to suffer such harm, damages and economic loss in the future.

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

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

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

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

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

140. Based on the foregoing, the Defendants are strictly liable to the Plaintiff for the design, manufacture, research, testing, advertising, promoting, marketing, labeling, sale, and distribution of a defective product, Eliquis.

141. The foregoing defects in the drug Eliquis were a substantial factor in causing Plaintiff's injuries.

142. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

143. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

144. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

FOURTH CAUSE OF ACTION
NEGLIGENCE AND GROSS NEGLIGENCE

145. Plaintiff incorporates by reference each preceding and succeeding paragraph

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

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

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

148. Defendants were well aware that if dosing instructions were not properly adjusted for age and information. Defendants' failure to provide a reasonably safe pharmaceutical, and Defendants' failure to adequately instruct or warn the users of the aforementioned dangers was negligent. Plaintiffs' injuries and damages were a foreseeable, direct and proximate result of the negligence of Defendants.

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

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

individuals;

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

c. As detailed above, failed to conduct sufficient post-marketing and surveillance of Eliquis in order to provide updated information to providers and patient populations, including currently available studies and adverse event information;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

151. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and

sale of Eliquis in that they:

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

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

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

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

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

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

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

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

i. Failed to warn that it is believed that a more tailored dose of Eliquis would increase safety and efficacy while reducing the risk of bleeding;

j. Were otherwise careless and/or negligent.

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

153. Defendants knew or should have known that consumers such as Plaintiff would

foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

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

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

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

157. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

FIFTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

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

159. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care to warn of the dangerous conditions and/or of the facts that made Eliquis likely to be dangerous.

160. Defendants owed a continuing duty to warn Plaintiff, prescribing physicians and the general public, of the dangers associated with Eliquis.

161. At all times relevant hereto, including the time period before Plaintiff ingested Eliquis, and during the time period in which he took Eliquis, Defendants knew or should have known that Eliquis was dangerous and created an unreasonable risk of bodily harm to consumers, including the Plaintiff.

162. The Defendants and their agents, servants and/or employees, breached their duty of care and were negligent by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Failing to provide proper, accurate or adequate warnings or labeling regarding all possible adverse side effects and health risks associated with the use of Eliquis;

b. Failing to provide proper, accurate or adequate warnings or labeling regarding the comparative severity and duration of the adverse side effects and health risks associated with the use of Eliquis;

c. Failing to provide proper, accurate or adequate rate of incidence or prevalence of irreversible bleeds;

d. Failing to accompany their product with all proper, accurate or adequate warnings or labeling regarding all possible adverse side effects, health risks and/or rate of incidence or prevalence of irreversible bleeds associated with the use of Eliquis and the comparative severity and duration of same;

e. Failing to provide proper, accurate or 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;

f. Failing to provide proper, accurate or 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;

g. Failing to provide proper, accurate or adequate warnings to the Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, that Eliquis's risk of harm was unreasonable and that there were safer and more effective alternative medications available to Plaintiff and other consumers;

h. Failing to provide proper, accurate or adequate warnings to the Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially serious and/or fatal dangerous side effects associated with the use of Eliquis.

i. Failed to warn that it is believed that a more tailored dose of Eliquis would increase safety and efficacy while reducing the risk of bleeding;

163. Eliquis was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks and reactions associated with Eliquis, including but not limited to the prevalence of irreversible bleeding, and other serious injuries and side effects despite Defendants' knowledge of the increased risk of these injuries over other anticoagulation therapies available.

164. Eliquis was defective 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 or death.

165. The warnings that were given by Defendants were not accurate, clear, complete, and/or were ambiguous.

166. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians of the risk of irreversible bleeding and other serious injuries and side effects, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk, as set forth herein.

167. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

168. Plaintiff was prescribed and used Eliquis for its intended purpose.

169. Plaintiff consumed the Eliquis as directed and without change in its form or substance.

170. Plaintiff could not have known about the dangers and hazards presented by Eliquis

171. Had Plaintiff received adequate warnings regarding the risks of Eliquis, he would not have used Eliquis.

172. Likewise, if Plaintiff's prescribing physicians received adequate warnings regarding the risks of Eliquis, Plaintiff's prescribing physicians would not have recommended, prescribed, dispensed, administered and/or relied on the drug, Eliquis.

173. Eliquis' ability to cause serious personal injuries and damages, such as those suffered by Plaintiff, was not due to any voluntary action or contributory negligence of Plaintiff.

174. As a direct and proximate result of Eliquis' defective, inaccurate, inadequate, incomplete and inappropriate warnings, Plaintiff has suffered severe physical injuries, harm, economic loss and damages as described herein.

175. As a direct and proximate result of the actions and omission of the Defendants

described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

176. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

177. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

178. Plaintiffs plead this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

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

180. Defendants designed, tested, manufactured, sold, distributed, marketed and promoted that Eliquis was were safe and efficacious for its intended uses. The Eliquis consumed by Plaintiff reached him without substantial change in its condition, and was used by Plaintiff as intended by Defendants. Defendants expressly and impliedly warranted that Eliquis was not unreasonably dangerous and instead were merchantable and fit for its intended use by Plaintiff. Further, Defendants expressly and impliedly warranted that Eliquis had been fully and adequately tested for long-term use and was, *inter alia,* safe to use in the treatment of

atrial fibrillation.

181. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Eliquis.

182. Defendants expressly warranted that Eliquis was safe and effective to Plaintiff and to other members of the general and consuming public.

183. Defendants marketed, promoted, sold, distributed and/or otherwise released into the stream of commerce, Eliquis as a safe and effective product.

184. Defendants expressly represented to Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, 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/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was accurately tested and fit for its intended use.

185. Eliquis does not conform to those representations made by Defendants because it is not safe and has numerous serious side effects, including life-threatening and irreversible bleeding events.

186. The Defendants and their agents, servants and/or employees, breached their express warranty by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Designing, manufacturing, advertising, promoting, marketing, labeling, selling, distributing and otherwise placing into the stream of commerce,

Eliquis in an defective and unreasonably dangerous condition;

b. Failing to warn and/or place accurate and adequate warnings and instructions on Eliquis;

c. Failing to adequately test Eliquis;

d. Failing to provide timely and adequate post-market warnings and instructions after they knew the risk of injury from Eliquis was higher than their pre-approval data showed.

187. Members of the medical community, including Plaintiff's prescribing physicians, relied upon the representations and warranties of the Defendants for use of Eliquis in recommending, prescribing and/or dispensing Eliquis to their patients, including the Plaintiff.

188. Plaintiff, and other members of the general and consuming public were the intended third-party beneficiaries of the warranty.

189. Plaintiff relied on the representations and warranties of the Defendants that Eliquis was safe and effective when he took the medication.

190. Plaintiff's injuries were the direct and proximate result of the Defendants' breach of their express warranties.

191. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

192. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

193. Defendants breached these warranties as Eliquis was not merchantable, was unfit

for its intended use, and was unreasonably dangerous when comparing the benefits Eliquis to the risks associated with its use. As a direct and proximate result of these breaches of warranties, Plaintiff was injured.

194. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

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

196. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Eliquis.

197. At all times that Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Eliquis, they knew of its intended uses to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reduce the risk of recurrence of DVT and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

198. Defendants impliedly represented and warranted Eliquis to Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, that Eliquis was safe and of merchantable quality and was fit for use for the ordinary purposes for which the product was to

be used, as set forth above.

199. Eliquis does not conform to those representations and warranties made by Defendants because it is not safe, not of merchantable quality, not fit for its intended uses, and has numerous serious side effects, including life-threatening and irreversible bleeding events.

200. Defendants' implied representations and warranties were false, misleading, and inaccurate because Eliquis was unsafe, unreasonably dangerous, improper, not of merchantable quality, not fit for its intended uses and defective.

201. Members of the medical community, including Plaintiff's prescribing physicians, relied upon the implied representations and warranties of the Defendants for use of Eliquis in recommending, prescribing and/or dispensing Eliquis to their patients, including the Plaintiff.

202. Plaintiff, and other members of the general and consuming public were the intended third-party beneficiaries of the warranty.

203. Plaintiff relied on the representations and warranties of the Defendants that Eliquis was safe and effective for treatment of non-valvular atrial fibrillation when he took the medication.

204. Defendants' breach of their implied warranties of merchantability and fitness for a particular purpose were the direct and proximate result of the Plaintiff's injuries.

205. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

206. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

207. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

208. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

EIGHTH CAUSE OF ACTION
FRAUD/FRAUDULENT CONCEALMENT

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

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

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

a. Website – www.eliquis.com -

https://www.eliquis.com/eliquis/hcp/stroke- risk-reduction-nvaf/efficacy - Defendants published "For patients with Nonvalvular Atrial Fibrillation (NVAF), Eliquis was proven effective in 2 Phase III studies." Defendants then cited to the "ARISTOTLE Study Primary Efficacy Endpoint" for justification of this representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to this 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 this 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 this data was fraudulently submitted to the FDA, and then Defendants used this fraudulent data to misrepresent the effectiveness of Eliquis when citing to the ARISTOTLE study in support of its claims of the medication's efficacy. As detailed above, the BMJ's findings dispute this data and no action has been taken on it.

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 this representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to this 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 this 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 this data was fraudulently submitted to the FDA, and then Defendants used this fraudulent data to misrepresent the effectiveness of Eliquis when citing to the ARISTOTLE study in support of its claims of the medication's efficacy. As detailed above, the BMJ's findings dispute this data and no action has been taken on it.

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 this representation as well as for its representation of its "superiority to warfarin." Defendants intentionally misled consumers and prescribers by citing to this 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 this 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 this data was fraudulently submitted to the FDA, and then Defendants used this 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, as the EMA and FDA have been suggesting;

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," there is no

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.

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

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

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

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

216. 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/or down-played warnings.

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

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

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

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

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

222. Eliquis was improperly marketed to Plaintiff and Plaintiff's prescribing

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

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

224. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiff. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Eliquis. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

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

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

227. Had Plaintiff been aware of the hazards associated with Eliquis, Plaintiff would

have employed appropriate blood monitoring, consumed a different anticoagulant with a better safety profile, or not have consumed the product that led proximately to Plaintiff's injuries.

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

229. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

230. 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.

231. 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.

232. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA, and the public in general to ensure the data from the ARISTOTLE study was not flawed or fraudlent.

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

234. Defendant had no reasonable ground to believe its statements regarding Eliquis' safety profile when compared to Warfarin were true.

235. Defendant had no reasonable ground to believe its statements regarding Eliquis' lack of need for blood monitoring were true.

236. Defendants intent was to bring the Eliquis product to market as quickly as possible without concern for the health or safety of users.

237. 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.

238. Plaintiff and Plaintiff's physician relied on these representations.

239. 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.

240. 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.

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

242. As a result of the foregoing, Plaintiff has been damaged in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

243. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

TENTH CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION LAWS

244. 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.

245. 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 California consumer protection laws.

246. Defendants engaged in unfair, deceptive, false and fraudulent acts and practices in violation of California law through its false and misleading promotion of Eliquis designed to induce Plaintiff to purchase and use Eliquis.

247. 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.

248. 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.

249. 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.

250. 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.

251. Defendants' conduct as described above was a material cause of Plaintiff's decision to purchase Eliquis.

252. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of California law the Plaintiffs suffered damages, including personal injuries, economic damages, and non-economic damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the award of punitive damages.

253. 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.

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

255. As a result of the foregoing, Plaintiff has been damaged in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

256. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

JURY TRIAL DEMANDED

257. Plaintiffs demands that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

WHEREFORE, Plaintiffs demand 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 Plaintiffs for the injuries Plaintiff has and or will suffer. Plaintiff further demands judgment against each of the Defendants for punitive damages. 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.

Napoli Shkolnik, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

Dated: February 2, 2017

SUPERIOR COURT
CIVIL CASE INFORMATION STATEMENT (CIS)

COUNTY: ☑ N ☐ K ☐ S CIVIL ACTION NUMBER: _____

Caption:
CARMEN FLORES v.
BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC.

Civil Case Code: CPRL

Civil Case Type: CPRL - Products Liability
(SEE REVERSE SIDE FOR CODE AND TYPE)

Name and Status of Party filing document:
CARMEN FLORES, Plaintiff

Document Type:(E.G.; COMPLAINT; ANSWER WITH COUNTERCLAIM)
Complaint

JURY DEMAND: YES ☑ NO ☐

ATTORNEY NAME(S):
James D. Heisman

ATTORNEY ID(S):
2746

FIRM NAME:
Napoli Shkolnik, LLC

ADDRESS:
919 North Market Street, Suite 1801
Wilmington, DE 09801

TELEPHONE NUMBER:
302-330-8025

FAX NUMBER:
646-843-7603

E-MAIL ADDRESS:
JHeisman@Napolilaw.com

IDENTIFY ANY RELATED CASES NOW PENDING IN THE SUPERIOR COURT OR ANY RELATED CASES THAT HAVE BEEN CLOSED IN THIS COURT WITHIN THE LAST TWO YEARS BY CAPTION AND CIVIL ACTION NUMBER INCLUDING JUDGE'S INITIALS:

N16C-02-077AML; N16C-02-150 AML; N16C-03-110 AML; N16C-03-111 AML; N16C-04-019 AML;
N16C-05-123; N15C-12-048 AML; N15C-12-213 AML; N15C-12-048 AML; N15C-12-048 AM'

EXPLAIN THE RELATIONSHIP(S):

N15C-12-213 AML; N15C-12-119 AML; N16C-12-078 AML; N17C-01-310 AML
N17C-01-140 AML; N17C-01-418 and N17C-01-388 AML

OTHER UNUSUAL ISSUES THAT AFFECT CASE MANAGEMENT:

(IF ADDITIONAL SPACE IS NEEDED, PLEASE ATTACH PAGE)

THE PROTHONOTARY WILL NOT PROCESS THE COMPLAINT, ANSWER, OR FIRST RESPONSIVE PLEADING IN THIS MATTER FOR SERVICE UNTIL THE CASE INFORMATION STATEMENT (CIS) IS FILED. THE FAILURE TO FILE THE CIS AND HAVE THE PLEADING PROCESSED FOR SERVICE MAY RESULT IN THE DISMISSAL OF THE COMPLAINT OR MAY RESULT IN THE ANSWER OR FIRST RESPONSIVE PLEADING BEING STRICKEN.

SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS) INSTRUCTIONS

CIVIL CASE TYPE

Please select the appropriate civil case code and case type (e.g., **CODE** - **AADM** and **TYPE** - **Administrative Agency**) from the list below. Enter this information in the designated spaces on the Case Information Statement.

APPEALS
AADM - Administrative Agency
ACER - Certiorari
ACCP - Court of Common Pleas
AIAB - Industrial Accident Board
APSC - Public Service Commission
AUIB - Unemployment Insurance Appeal Board

COMPLAINTS
CABT – Abatement
CASB – Asbestos
CAAA - Auto Arb Appeal
CMIS - Civil Miscellaneous
CACT - Class Action
CCON - Condemnation
CCLD - Complex Commercial Litigation Division **(NCC ONLY)**
CDBT - Debt/Breach of Contract
CDEJ - Declaratory Judgment
CDEF - Defamation
CEJM - Ejectment
CATT - Foreign & Domestic Attachment
CFJG - Foreign Judgment
CFRD - Fraud Enforcement
CINT - Interpleader
CLEM - Lemon Law
CLIB - Libel
CMAL - Malpractice
CMED - Medical Malpractice
CPIN - Personal Injury
CPIA - Personal Injury Auto
CPRL - Products Liability
CPRD - Property Damage
CRPV - Replevin
CSPD - Summary Proceedings Dispute
CCCP - Transfer from CCP
CCHA - Transfer from Chancery

MASS TORT
CBEN - Benzene Cases
CPEL - Pelvic Mesh Cases
CPLX - Plavix Cases
CXAR - Xarelto Cases

INVOLUNTARY COMMITMENTS
INVC- Involuntary Commitment

MISCELLANEOUS
MAGM - AG Motion - Civil/Criminal Investigations *
MADB - Appeal from Disability Board *
MAFF - Application for Forfeiture
MAAT - Appointment of Attorney
MGAR - Appointment of Guardianship
MCED - Cease and Desist Order
MCON - Civil Contempt/Capias
MCVP - Civil Penalty
MSOJ - Compel Satisfaction of Judgment
MSAM - Compel Satisfaction of Mortgage
MCTO - Consent Order
MIND - Destruction of Indicia of Arrest *
MESP - Excess Sheriff Proceeds
MHAC - Habeas Corpus
MTOX - Hazardous Substance Cleanup
MFOR - Intercept of Forfeited Money
MISS - Issuance of Subpoena
MLEX - Lien Extension
MMAN - Mandamus
MWIT - Material Witness *
MWOT - Material Witness - Out of State
MRAT - Motion for Risk Assessment
MROP - Petition for Return of Property
MCRO - Petition Requesting Order
MROD - Road Resolution
MSEL - Sell Real Estate for Property Tax
MSEM - Set Aside Satisfaction of Mortgage
MSSS - Set Aside Sheriff's Sale
MSET - Structured Settlement
MTAX - Tax Ditches
MREF - Tax Intercept
MLAG - Tax Lagoons
MVAC - Vacate Public Road
MPOS - Writ of Possession
MPRO - Writ of Prohibition

MORTGAGES
MCOM - Mortgage Commercial
MMED - Mortgage Mediation
MORT - Mortgage Non-Mediation (Res.)

MECHANICS LIENS
LIEN - Mechanics Lien

* Not eFiled

DUTY OF THE PLAINTIFF

Each plaintiff/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the complaint.

DUTY OF THE DEFENDANT

Each defendant/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the answer and/or first responsive pleading.

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

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

PLAINTIFFS' ANSWERS TO FORM 30 INTERROGATORIES

1. Give the name and present or last-known residential and employment address and telephone number of each eyewitness to the incident which is the subject of the litigation.

   ANSWER:

   To be supplemented, if applicable.

2. Give the name and present or last-known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

   ANSWER:

   Plaintiff, CARMEN FLORES, who may be contacted only through the undersigned counsel. Plaintiff's treating physicians. The names and contact information of said treating physicians will be supplied by plaintiff. To be supplemented, if applicable.

3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last-known residential and employment addresses and telephone numbers of the persons who made said interviews and the names and present or last-known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

   ANSWER: None.

4. Identify all photographs, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last-known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

   ANSWER: None currently in possession.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, describe by type the experts whom the party expects to retain in connection with the litigation.

   ANSWER: Experts in epidemiology, Experts in blood clotting, FDA Regulatory Experts, Causation Experts, Damages Experts and other experts will be retained.

6. Give a brief description of any insurance policy, including excess coverage, that is or may be applicable to the litigation, including:
   a. The name and address of all companies insuring the risk;
   b. The policy number(s);
   c. The type of insurance;
   d. The amounts of primary, secondary, and excess coverage.

   ANSWER: Not Applicable

7. Give the name, professional address, and telephone number of all physicians, chiropractors, psychologists, and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident at issue in this litigation.

   ANSWER:

   To be supplemented.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman

James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

DATED: February 2, 2017

EFiled: Feb 02 2017 02:38PM EST
Transaction ID 60154371
Case No. N17C-02-024 AML

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

CARMEN FLORES, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC., Defendants.	C.A. No.: JURY TRIAL DEMANDED

PRAECIPE

PLEASE ISSUE Summons and Complaint through the Sheriff of New Castle County to the defendants at the addresses indicated herein:

BRISTOL-MYERS SQUIBB COMPANY
c/o The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

PFIZER, INC.
c/o The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 300-4625
JHeisman@NapoliLaw.com
Attorneys for Plaintiff

DATED: February 2, 2017

EFiled: Feb 02 2017 02:38PM EST
Transaction ID 60154371
Case No. N17C-02-024 AML

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

CARMEN FLORES, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC., Defendants.	C.A. No.: JURY TRIAL DEMANDED

SUMMONS

THE STATE OF DELAWARE,
TO THE SHERIFF OF NEW CASTLE COUNTY:

YOU ARE COMMANDED:

To summon the above defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiffs' attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff).

Dated:

SUSAN A. HEARN
Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN
Prothonotary

_____
Per Deputy