

**SUPERIOR COURT  
CIVIL CASE INFORMATION STATEMENT (CIS)**

Filed: Jan 09 2017 01:07PM EST  
Transaction ID 60042071  
Case No. N17C-01-140 AML



COUNTY: N K S

CIVIL ACTION NUMBER: \_\_\_\_\_

Caption: (Entire Caption) : MICHAEL WATKINS and DANNA WATKINS v. BRISTOL-MYERS SQUIBB COMPANY; and PFIZER, INC.,

Civil Case Code: CPRL

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

Name and Status of Party filing document:

MICHAEL WATKINS and DANNA WATKINS, Plaintiff

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

Complaint

JURY DEMAND: Yes  No

ATTORNEY NAME(S):  
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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:  
Goodpaster N15C-12-119; Barb N 15C-12-213; Tobin N15C-12-048; Carr N16C-02-077; Hold N16C-02-150; Deitrich N16C-03-110; Daniels N16C-03-111; Carew N16C-04-019; Buck N16C-12-078 and Jackson N16C-05-123 AML

EXPLAIN THE RELATIONSHIP(S):

OTHER UNUSUAL ISSUES THAT AFFECT CASE MANAGEMENT:

**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.

<p><b>APPEALS</b>  AADM - Administrative Agency  ACER - Certiorari  ACCP - Court of Common Pleas  AIAB - Industrial Accident Board  APSC - Public Service Commission  AUIB - Unemployment Insurance Appeal Board</p> <p><b>COMPLAINTS</b>  CASB - Asbestos  CAAA - Auto Arb Appeal  CMIS - Civil Miscellaneous  CACT - Class Action  CCON - Condemnation  CCLD - Complex Commercial Litigation Division (<b>NCC ONLY</b>)  CDBT - Debt/Breach of Contract  CDEJ - Declaratory Judgment  CDEF - Defamation  CEJM - Ejectment  CATT - Foreign &amp; 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</p> <p><b>MASS TORT</b>  CBEN - Benzene Cases  CPEL - Pelvic Mesh Cases  CPRA - Pradaxa Cases  CSER - Seroquel Cases</p> <p><b>INVOLUNTARY COMMITMENTS</b>  INVC - Involuntary Commitment</p>	<p><b>MISCELLANEOUS</b>  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  MCDR - Child Death Review  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</p> <p><b>MORTGAGES</b>  MCOM - Mortgage Commercial  MMED - Mortgage Mediation  MORT - Mortgage Non-Mediation (Res.)</p> <p><b>MECHANICS LIENS</b>  LIEN - Mechanics Lien</p>
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\* 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

MICHAEL WATKINS and DANNA WATKINS,

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, MICHAEL WATKINS, 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 this 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  
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JHeisman@NapoliLaw.com  
*Attorney for Plaintiff*

DATED: January 5, 2017



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

MICHAEL WATKINS and DANNA WATKINS,

Plaintiffs,

v.

BRISTOL-MYERS SQUIBB COMPANY and  
PFIZER INC.,

Defendants.

C.A. No.:

JURY TRIAL DEMANDED

COMES NOW Plaintiffs, MICHAEL WATKINS and DANNA WATKINS, as wife who by and through the undersigned counsel hereby submit 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 MICHAEL WATKINS as a result of her exposure to the prescription drug ELIQUIS®. In support of this Complaint, Plaintiffs allege the following:

**COMPLAINT**

**I. COMMON ALLEGATIONS**

1. Plaintiffs, MICHAEL WATKINS and DANNA WATKINS, at all times relevant hereto, were and are citizens and residents of the State of Texas, who suffered personal injuries and loss of consortium as a result of plaintiff, MICHAEL WATKINS's use of Eliquis.

2. Defendant BRISTOL-MYERS SQUIBB COMPANY ("BMS") is a company organized under the laws of Delaware with a principal place of business at 345 Park Avenue, New York, New York. Its registered agent for service of process is: c/o The Corporation Trust



Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Defen

BMS is the holder of the approved New Drug Application (“NDA”) for Eliquis as well as the supplemental NDA.

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

4. 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.

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

6. 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.

7. 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.”

#### **NATURE OF THE CASE**

8. This action is brought on behalf of Plaintiff MICHAEL WATKINS and DANNA WATKINS. Plaintiff, MICHAEL WATKINS, was prescribed Eliquis, also known as apixaban,



to reduce the risk of stroke and embolism due to atrial fibrillation. On or about January 2015, Plaintiff MICHAEL WATKINS suffered a cerebral bleed.

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

10. 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.

11. 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.

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

13. 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.



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

### **FACTUAL BACKGROUND**

15. 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.

16. 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.

17. 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.

18. 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 Ratio (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.





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

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

21. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Eliquis as an oral anticoagulant, also known as a Factor Xa inhibitor.

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 Savaya (edoxaban) in 2015. Defendants received FDA approval to market Eliquis in 2012 (NDA 202155).

23. 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.

24. Eliquis has two dosages—2.5 mg and 5 mg-- approved by the FDA to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. The FDA, in



March 2014, expanded the indicated use for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients who have undergone hip or knee replacement. And in August 2014, the FDA label added that Eliquis is indicated for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. Among the uses for which Defendants obtained permission to market Eliquis was in the treatment of atrial fibrillation. Approval of Eliquis was based in large part on clinical trials known as ARISTOTLE.

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

26. Sadly, Defendants and their agents committed fraud in their conduct of the ARISTOTLE study, by *inter alia*, concealing side effects that occurred in test users of Eliquis; concealing a death which went unreported (whereas one purpose of the study was to study the rate of death in Eliquis users compared to others on Coumadin); concealing loss of subjects to follow up; concealing major dispensing errors including indicating that certain subjects were getting Eliquis when they were not; having poor overall quality control; and



changing and falsifying records, including records disappearing just before the FDA made a site visit, reportedly on the order of an employee of BMS (who was later terminated).

27. Defendants received FDA approval to market Eliquis in 2012 (NDA 202155).

28. Among the uses for which it obtained permission to market Eliquis was in the treatment of atrial fibrillation.

29. 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.

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

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

32. 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 2 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.

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

34. Instead of admitting the major errors and frauds involved in the ARISTOTLE study, Defendants misleadingly stated publically that they were submitting “additional data” to the FDA, and to this date have never publically acknowledged the missing and incorrect data submitted to the FDA, which would be of concern to prescribing physicians and the public.

35. After employees of Defendants wrote and submitted an article based on the ARITOTLE 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.

36. 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.

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

38. 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 b levels of the patient did not need to be monitored.

39. In the course of these direct-to-consumer advertisements, Defendants overstated the efficacy of Eliquis with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Eliquis, and that such irreversibility would have life-threatening and fatal consequences.

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

41. 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.

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

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

44. Based upon information and belief, prior to Plaintiff’s use of Eliquis, Plaintiff’s prescribing physician would have received promotional materials and information from sales representatives of Defendants that Eliquis was just as effective as warfarin (Coumadin) in reducing



strokes in patients with non-valvular atrial fibrillation, and was more convenient, without also adequately informing prescribing physicians of the 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, an 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 pharmaceutical lacks an appropriate safety shield which has become a standard in the pharmaceutical industry.

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

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

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



48. Defendants' product labeling and prescribing information for Eliquis:
- (a) failed to investigate, research, study and define fully and adequately, the safety profile of Eliquis;
  - (b) failed to provide adequate warnings about the true safety risks associated with the use of Eliquis;
  - (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamics variability of Eliquis and its effects on the degree of anticoagulation in a patient;
  - (d) failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis;
  - (e) failed to disclose in the "Warnings" section that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis;
  - (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 increased risk of suffering a bleeding event, requiring blood transfusions in those taking Eliquis;



- (k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Eliquis and to continue testing and monitoring of renal functioning periodically while the patient is on Eliquis;
- (l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Eliquis and to continue testing and monitoring of hepatic functioning periodically while the patient is on Eliquis;
- (m) failed to include a “BOXED WARNING” about serious bleeding events associated with Eliquis;
- (n) failed to include a “BOLDED WARNING” about serious bleeding events associated with Eliquis; and
- (o) in their “Medication Guide” intended for distribution to patients, to whom Eliquis has been prescribed, Defendants failed to 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 permanent disabling, life-threatening or fatal consequences.

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

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

51. From the date Defendants received FDA approval to market Eliquis, Defendants made, distributed, marketed, and sold Eliquis without adequate warning to Plaintiff’s prescribing physician 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, that Defendants had not adequately conducted complete and proper testing and studies of Eliquis with regard to severe side effects, specifically life-threatening bleeding.

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

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

54. 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.

55. By reason of the foregoing acts and omissions, Plaintiffs have endured and continues to suffer emotional and mental anguish, loss of support, loss of services, loss of accumulations, medical expenses, and other economic and non-economic damages as a result of the actions and inactions of the Defendants.

**FIRST CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS (NEGLIGENCE)**

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

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



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

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

- (a) Manufacturing, producing, promoting, formulating, creating and designing Eliquis without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and designing Eliquis without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not Eliquis was safe for use; in that Defendants herein knew or should have known that Eliquis was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling Eliquis without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Eliquis;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use Eliquis;
- (g) Failing to test Eliquis and failing to adequately, sufficiently and properly test Eliquis;



- (h) Negligently advertising and recommending the use of Eliquis without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that Eliquis was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently representing that Eliquis had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (k) Negligently designing Eliquis in a manner which was dangerous to its users;
- (l) Negligently manufacturing Eliquis in a manner which was dangerous to its users;
- (m) Negligently producing Eliquis in a manner which was dangerous to its users;
- (n) Negligently assembling Eliquis in a manner which was dangerous to its users;
- (o) Concealing information from the Plaintiff in knowing that Eliquis was unsafe, dangerous and non-conforming with FDA regulations;
- (p) Improperly concealing and misrepresenting information from the Plaintiff, healthcare professionals, and the FDA, concerning the severity of risks and dangers of Eliquis compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (q) Negligently represented that one dose size fit all patients, whereas they knew or should have known that proper dosage depending on individualizing factors in users.
- (r) failed to investigate, research, study, and define, fully and adequately, the safety profile of Eliquis;
- (s) failed to provide adequate warnings about the true safety risks associated with the use of Eliquis;
- (t) 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; failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis;

- (u) 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;
- (v) in their “Medical 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;
- (w) 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;
- (x) failed to warn regarding the need for more comprehensive, more regular medical monitoring to ensure early discovery and potentially serious side effects; and
- (y) Failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly and inaccurately that one dosage fit all patients.

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

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

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

63. 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.

64. Defendants negligently compared the safety risk and dangers of Eliquis with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-



valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylax DVT for patients undergoing hip and knee replacement surgery.

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

- (a) Failed to use due care in designing and manufacturing Eliquis so as to avoid the aforementioned risks to individuals when Eliquis was used for treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (b) Failed to accompany their product with proper and accurate warnings regarding all possible adverse side effects associated with the use of Eliquis;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and malfunction of Eliquis;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Eliquis;
- (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Eliquis;
- (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Eliquis, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;
- (h) Failed to instruct how to adjust the dosage to the particular patient and instead stated misleadingly that one dosage fit all patients;
- (i) Were otherwise careless and negligent.



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

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

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

69. 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, and expenses for hospitalization and loss of earnings.

70. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages including medical expenses; the loss of accumulations and other economic and non-economic damages.

71. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged.

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



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

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

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

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

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

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



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

79. At the time of the Plaintiff's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended, namely for his diagnosed atrial fibrillation.

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

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

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

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

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

85. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

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





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

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

89. 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.

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

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

92. The aforementioned defects in Defendants' drug Eliquis were a substantial factor in causing Plaintiff's injuries.



93. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including life-threatening bleeding, as well as other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and ultimately death.

94. 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, and expenses for hospitalization, loss of earnings and ultimately death.

95. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including medical expenses; the loss of accumulations and other economic and non-economic damages...

96. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

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

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

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

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



100. As a direct and proximate result of the breach of said warranties, Plaintiff Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

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

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

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

104. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Eliquis was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

106. 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, and loss of earnings.

107. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including medical expenses; and other economic and non-economic damages. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

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

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

109. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Eliquis and have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Eliquis to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

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

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

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



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

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

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

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

117. 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, and expenses for hospitalization and loss of earnings.

118. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including medical expenses; and other economic and non-economic damages. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

**FIFTH CAUSE OF ACTION AS AGAINST DEFENDANTS**  
**(FRAUDULENT MISREPRESENTATION)**

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



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

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

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

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

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

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



126. Defendants knew and were aware or should have been aware that Eliquis had been sufficiently tested, was defective in nature, and that it lacked adequate and sufficient warnings.

127. Defendants knew or should have known that Eliquis had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and down-played warnings.

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

129. 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, and expenses for hospitalization and loss of earnings.

130. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

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

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

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



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

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

- (a) that Eliquis was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (b) that the risks of adverse events with Eliquis were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (c) that the risks of adverse events with Eliquis were not adequately tested and known by Defendants;
- (d) that Defendants were aware of dangers in Eliquis, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (e) that Eliquis was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- (f) that patients needed to be monitored more regularly than normal while using Eliquis;
- (g) that Eliquis was manufactured negligently;
- (h) that Eliquis was manufactured defectively;
- (i) that Eliquis was manufactured improperly;





- (j) that Eliquis was designed negligently;
- (k) that Eliquis was designed defectively; and,
- (l) That Eliquis was designed improperly.

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

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

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

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

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



140. 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, and loss of earnings.

141. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

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

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

143. 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.

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

145. 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.

146. 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.



147. 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, and loss of earnings.

148. As a result of the foregoing acts and omissions, Plaintiff's estate has suffered and incurred damages, including medical expenses; and other economic and non-economic damages...

149. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

**EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS**  
**(FRAUD)**

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

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

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



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

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

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

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

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



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

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

160. These representations were all false and misleading.

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

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



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

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

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

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



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

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

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

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

170. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and the FDA, and were made in order to induce the Plaintiff and Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and prescribe Eliquis.

171. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and safety concerns of Eliquis to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke



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

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

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

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

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

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





replacement surgery, and were thereby induced to purchase, use and rely on Defendants' Eliquis.

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

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

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

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

181. 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, and expenses for hospitalization, loss of earnings and ultimately death.

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



183. By reason of the foregoing, Plaintiffs have suffered injures and damage alleged herein.

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

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

185. 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 Kansas consumer protection laws.

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

187. 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.

188. 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.



189. Defendants uniformly communicated the purported benefits of Eliquis v 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.

190. 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.

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

192. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of Kansas law the Plaintiff and Plaintiff 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.

193. 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, and loss of earnings...

194. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including medical expenses; the loss of accumulations and other economic and non-economic damages.



195. By reason of the foregoing, Plaintiffs have suffered injuries and damage alleged herein.

**TENTH CAUSE OF ACTION**

**LOSS OF CONSORTIUM, EMOTION DISTRESS & LOSS ENJOYMENT OF LIFE**

196. 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, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

197. At all relevant times hereto, where applicable, Plaintiff, DANNA WATKINS, was the spouse of Plaintiff, MICHAEL WATKINS, and in that capacity has suffered injuries and losses as a result of her husband injuries from Eliquis.

198. For the reasons set forth herein, because of the injury to Plaintiff, MICHAEL WATKINS, and Plaintiff, DANNA WATKINS has suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection.

199. Plaintiff alleges that during their marriage after her husband's hemorrhage, their marital relationship was impaired and depreciated, and the marital association between wife and wife was altered.

200. Plaintiff has suffered great emotional pain and mental anguish as well as lost enjoyment of life as a result of the acts of Defendants alleged herein.

201. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe emotional distress, economic losses and other damages for which she is entitled to compensatory and equitable damages and declaratory relief



in an amount to be proven at trial. Defendants are liable to Plaintiffs jointly and severally for general, special and equitable relief to which is entitled by law.

**WHEREFORE**, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have and will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand 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)  
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JHeisman@NapoliLaw.com  
*Attorney for Plaintiff*

Dated: January 5, 2017



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

MICHAEL WATKINS and DANNA WATKINS,

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: January 5, 2017





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*