



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

KENNETH M. KUBLER as Personal )  
Representative of the Estate of VIRGINIA )  
R. KUBLER and KENNETH M. )  
KUBLER, Individually, )  
 )  
Plaintiff, )

C.A. NO.

JURY TRIAL DEMANDED

v. )  
)

BRISTOL-MYERS SQUIBB COMPANY; )  
PFIZER INC, )  
 )  
Defendants. )

**COMPLAINT**

**COMMON ALLEGATIONS**

1. Plaintiffs, VIRGINIA M. KUBLER (Ingesting Plaintiff and “Decedent”), and KENNETH M. KUBLER (Plaintiff and Spouse), at all relevant times, were residents of the State of Texas.

2. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as “BMS”) is a company organized under the laws of Delaware with a principal place of business located at 345 Park Avenue, New York, New York, 10145-0037. BMS may be served by serving its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Defendant BMS is the holder of the approved New Drug Application (“NDA”) for Eliquis as well as the supplemental NDA.

3. As part of its business, BMS was and is involved in the research, development, sales, 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 E. 42<sup>nd</sup> Street, New York, New York. Pfizer Inc, may be served by serving its registered agent: The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 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 BMS and Pfizer entered into a worldwide collaboration to “commercialize” apixaban (Eliquis), which they have promoted as combining BMSs “long-standing strengths in cardiovascular drug development and commercialization” with PFIZER’S “global scale and expertise in this field”.

### **NATURE OF THE CASE**

8. On or about February 26, 2015, Decedent was first prescribed and began taking Eliquis, also known as apixaban, upon direction of Decedent’s physician for treatment of atrial fibrillation. Subsequently, as a direct result of

Decedent's ingestion of Eliquis, Decedent suffered a gastrointestinal bleed, anemia, and/or other internal bleeding and injuries and on or about March 23, 2015 was treated and admitted to the Medical Center of Lewisville, 10030 North MacArthur Boulevard, 75063-5001. Virginia R. Kubler died on April 28, 2015.

9. As a direct and proximate result of Defendants' conduct, Decedent 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 Decedent, the FDA, the public in general and the medical community, including Decedent's prescribing doctor.

13. These representations were made by Defendants with the intent of defrauding and deceiving Decedent, the public in general, and the medical and healthcare community including Decedent'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, departed indifference to health, safety and welfare of the Decedent herein.

14. As a result of the foregoing acts and omissions, the Decedent 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. 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 Factor Xa inhibitor.

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

17. Among the uses for which it obtained permission to market Eliquis was in the treatment of prevention of any potential thromboembolic events.

18. Approval of Eliquis was based in large part on clinical trials known as ARISTOTLE.

19. The ARISTOTLE study was conducted under the supervision and control of defendants, in various companies, including China.

20. Defendants, as means of cutting costs, chose incompetent and untrustworthy agents in China to conduct the ARISTOTLE study.

21. 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.

22. 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.

23. Defendants market Eliquis as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. Defendants emphasize the supposed benefits 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.

24. When the application by to the FDA by Defendants 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. Prior to Decedent's use of Eliquis, Decedent became aware of the promotional materials described herein.

32. Prior to Decedent's use of Eliquis, Decedent's prescribing physician received promotional materials and information from sales representatives of Defendants that Eliquis was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Eliquis.

33. At all times relevant hereto, Defendants also failed adequately to warn emergency room doctors, surgeons, and other critical care and 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.

34. 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.

35. 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.

36. Defendants' product labeling and prescribing information for Eliquis:
- (a) failed to investigate, research, study and define, fully and adequately, the safety profile of Eliquis;
  - (b) failed to provide adequate warnings about the true safety risks associated with the use of Eliquis;
  - (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Eliquis and its effects on the degree of anticoagulation in a patient;
  - (d) failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis;



- (e) failed to 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 Decedent'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 permanently disabling, life- threatening or fatal consequences.

37. 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.

38. 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.

39. From the date Defendants received FDA approval to market Eliquis, Defendants made, distributed, marketed, and sold Eliquis without adequate warning to Decedent's prescribing physicians or Decedent 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.

40. 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.

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

42. 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.

43. By reason of the foregoing acts and omissions, Decedent has endured and continues to suffer emotional and mental anguish, loss of support, loss of services, loss of accumulations, medical and funeral expenses, and other economic and non-economic damages stemming from the death of the Decedent, as a result of the actions and inactions of the Defendants.

### **FIRST CAUSE OF ACTION**

#### **AS AGAINST THE DEFENDANTS (NEGLIGENCE)**

44. Plaintiff incorporates by reference each and every preceding paragraph of this Complaint as if fully set forth herein and further alleges:

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

46. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale,

testing, quality assurance, quality control, and distribution of Eliquis into interstate commerce in that Defendants knew or should have known that using Eliquis created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and shortened life expectancy.

47. 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 Decedent in knowing that Eliquis was unsafe, dangerous and non-conforming with FDA regulations;
- p. Improperly concealing and misrepresenting information from the Decedent, 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.

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

49. 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 nonvalvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

50. 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 nonvalvular 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 Decedent 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 Decedent, 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.

51. 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 Decedent.

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

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

54. As a result of the foregoing acts and omissions, the Decedent 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 and death.

55. By reason of the foregoing, Decedent has suffered injuries and damages as alleged.

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

56. Decedent incorporates by reference each and every preceding paragraph of this Complaint as if fully set forth herein and further alleges:

57. 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 Decedent. 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.

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

59. 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.

60. 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.

61. 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.

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

63. At the time of the Decedent's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended, namely for her post-pacemaker placement.

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

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

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

67. 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.

68. 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.

69. 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 Decedent in particular; and Defendants are therefore strictly liable for the injuries sustained by the Decedent.

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

71. 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.

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

73. 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.

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

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

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

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

78. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

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

79. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if fully set forth herein and further alleges:

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

81. 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.

82. As a direct and proximate result of the breach of said warranties, Decedent suffered personal injuries, other harm and economic loss.

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

84. 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.

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

86. Defendants expressly represented to Decedent, Decedent'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.

87. 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.

88. As a result of the foregoing acts and omissions, Decedent 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.

89. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

#### **FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS**

##### **(BREACH OF IMPLIED WARRANTIES)**

90. Plaintiff incorporates by reference each of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges:

91. 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.

92. At the time Defendants marketed, sold and distributed Eliquis for use by Decedent, 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.

93. 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.

94. 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.

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

96. Decedent and Decedent'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.

97. 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.

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

99. As a result of the foregoing acts and omissions, the Decedent 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.

100. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.



## **FIFTH CAUSE OF ACTION AS AGAINST DEFENDANTS**

### **(FRAUDULENT MISREPRESENTATION)**

101. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if fully set forth herein and further alleges:

102. The Defendants falsely and fraudulently represented to the medical and healthcare community, Decedent's prescribing physician, and to the Decedent, 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.

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

104. 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.

105. 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 nonvalvular 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 Decedent herein.

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

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

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

109. 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.

110. Defendants brought Eliquis to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Decedent.

111. As a result of the foregoing acts and omissions, the Decedent 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.

112. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

## **SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS**

### **(FRAUDULENT CONCEALMENT)**

113. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if fully set forth herein and further alleges:

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

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

116. In representations to Decedent, and Decedent'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.

117. Defendants were under a duty to disclose to Decedent, and Decedent'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.

118. 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 Decedent, in particular.

119. Defendants' concealment and omissions of material facts concerning the safety of Eliquis was made purposefully, willfully, wantonly, and recklessly, to mislead Decedent, and Decedent'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.

120. Defendants knew that Decedent, and Decedent'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.

121. Decedent, as well as Decedent'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.

122. 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.

123. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

## **SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS**

### **(NEGLIGENT MISREPRESENTATION)**

124. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if fully set forth herein and further alleges:

125. Defendants had a duty to represent to the medical and healthcare community, and to the Decedent, 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.

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

127. 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.

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

129. As a result of the foregoing acts and omissions, the Decedent 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.

130. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

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

131. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if fully set forth herein and further alleges:

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

133. 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 Decedent, Decedent'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.

134. 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 Decedent.

135. 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 Decedent, as well as Decedent's respective healthcare providers and the FDA.

136. The information distributed to the public, the FDA, and the Decedent, 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.



137. The information distributed to the public, the FDA, and the Decedent, 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.

138. The information distributed to the public, the FDA, and the Decedent, 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.

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

140. The information distributed to the public, the FDA, and the Decedent, 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.

141. These representations were all false and misleading.

142. 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.

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

144. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Decedent, 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.

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

146. 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.

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

and did not pose risks, dangers, or hazards above and beyond those identified and associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

149. Defendants made claims and representations in their documents submitted to the FDA, to the public, to healthcare professionals, and the Decedent 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.

150. 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.

151. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Decedent, including Decedent's

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

152. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and safety concerns of Eliquis to the public at large, the Decedent 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.

153. 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.

154. 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 Decedent, as well as her respective healthcare professionals into a sense of security so that Decedent would rely on the representations made by Defendants, and purchase, use and rely on Eliquis and

that Decedent's respective healthcare providers would dispense, prescribe, and recommend the same.

155. 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 Decedent, as well as Decedent's respective healthcare professionals would rely upon the information being disseminated.

156. Defendants utilized direct to consumer advertising to market, promote, and advertise Eliquis.

157. The Decedent and Decedent'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' drug Eliquis.

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

159. That the Decedent 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 Decedent with reasonable diligence have discovered the true facts.

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

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

162. As a result of the foregoing acts and omissions, the Decedent 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.

163. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

**NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS**

**(VIOLATION OF CONSUMER PROTECTION LAWS)**

164. Plaintiff incorporates by reference each preceding paragraph of this Complaint as if more fully set forth herein and further alleges:

165. 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 Texas consumer protection laws.

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

167. 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.

168. 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 Decedent to purchase and use Eliquis.

169. 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 Decedent in the marketing and advertising campaign described herein.

170. 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.

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

172. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of Texas law the Decedent 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.

173. As a result of the foregoing acts and omissions, the Decedent 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.

174. By reason of the foregoing, Decedent has suffered injuries and damages as alleged herein.

### **LOSS OF CONSORTIUM**

175. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

176. Plaintiff was at all times relevant hereto the spouse of Decedent.

177. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of Decedent spouse's companionship and society, and accordingly, Plaintiff has been caused great mental anguish.

### **WRONGFUL DEATH**

177. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

178. As a result of the acts and/or admissions of the Defendants as set forth herein, Decedent suffered serious emotional and bodily injuries.

179. Decedent's special administrators and/or proposed special administrators and/or personal representatives are entitled to recover damages as Decedent would have if she was living as a result of the acts and/or omissions of the Defendants.

**WHEREFORE**, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate

the Plaintiff for the injuries Plaintiff has and will suffer. Plaintiff further demands 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.

MARC J. BERN & PARTNERS LLP

By: *Diane M. Coffey*  
Diane M. Coffey (DE Bar ID No.200001)  
Lincoln Square  
300 North Market Street  
Building One, Suite 204  
Wilmington, DE 19801  
(302) 256-5993  
*Attorneys for Plaintiffs*  
dcoffey@bernllp.com

Dated: March 2, 2017



SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS)

COUNTY: (N) K S

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

<p><b>Caption:</b></p> <p>KENNETH M. KUBLER as Personal Representative of the Estate of VIRGINIA R. KUBLER, and KENNETH M. KUBLER, Individually,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>BRISTOL-MYERS SQUIBB COMPANY, and PFIZER, INC.,</p> <p style="text-align: center;">Defendants.</p> <p><b>Attorney Name(s):</b> Diane Coffey, Esquire</p> <p><b>Attorney ID(s):</b> 200001</p> <p><b>Firm Name(s):</b> Marc J. Bern &amp; Partners LLP</p> <p><b>Office Address:</b> Lincoln Square 300 North Market Street Building One, Suite 204 Wilmington, DE 19801</p> <p><b>Telephone Number:</b> 302-256-5993</p> <p><b>Fax Number:</b></p> <p><b>E-Mail Address:</b> dcoffey@bernlip.com</p>	<p><b>Civil Case Code:</b> <u>CPRL</u></p> <p><b>Civil Case Type:</b> Product Liability</p> <p><b>Name and Status of Party Filing Lawsuit:</b></p> <p>KENNETH M. KUBLER as Personal Representative of the Estate of VIRGINIA R. KUBLER and KENNETH M. KUBLER, Individually,</p> <p><b>Document Type:</b></p> <p>Complaint _____</p> <p><b>Jury Demand:</b> Yes <u> X </u> No _____</p> <p><b>Identify Any Related Cases Now Pending in the Superior Court by Caption and Civil Action Number Including Judge's Initials:</b></p> <p><b>Explain the Relationship(s):</b></p> <p><b>Other Unusual Issues that Affect Case Management:</b></p>
---	---

**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 TO 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.**



**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

KENNETH M. KUBLER as Personal  
Representative of the Estate of  
VIRGINIA R. KUBLER and  
KENNETH M. KUBLER, Individually,

C.A. No.:

Plaintiffs,

JURY TRIAL DEMANDED

v.

BRISTOL-MYERS SQUIBB  
COMPANY; PFIZER, INC.,

Defendants.

**PLAINTIFF'S 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: KENNETH M. KUBLER**  
3427 Shady Oaks  
Flower Mound, Texas 75022

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.

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, if applicable.

**MARC J. BERN & PARTNERS LLP**

**By:** /s/ Diane M. Coffey  
Diane M. Coffey (No.200001)  
Lincoln Square  
300 North Market Street  
Building One, Suite 204  
Wilmington, DE 19801  
(302) 256-5993  
dcoffey@bernllp.com  
*Attorney for Plaintiff*

Dated: March 2, 2017



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

KENNETH M. KUBLER as Personal	)	C.A. NO.
Representative of the Estate of VIRGINIA R.	)	
KUBLER and KENNETH M. KUBLER,	)	JURY TRIAL DEMANDEI
Individually,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
BRISTOL-MYERS SQUIBB COMPANY,	)	
and PFIZER, INC.,	)	
	)	
Defendants.	)	
	)	

**NEW CASTLE COUNTY 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**

The Corporation Trust Company  
Corporation Trust Center  
1209 Orange Street  
Wilmington, DE 19801

**PFIZER, INC.**

The Corporation Trust Company  
Corporation Trust Center  
1209 Orange Street  
Wilmington, DE 19801

**MARC J. BERN & PARTNERS LLP**

**By:** /s/ Diane M. Coffey  
Diane M. Coffey, Esquire  
Delaware Bar ID No. 200001  
Lincoln Square  
300 North Market Street  
Building One, Suite 204  
Wilmington, DE 19801  
(302) 256-5993  
*Attorneys for Plaintiffs*

DATED: March 2, 2017





IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

KENNETH M. KUBLER as Personal  
Representative of the Estate of VIRGINIA R.  
KUBLER and KENNETH M. KUBLER,  
Individually,

Plaintiffs,

v.

BRISTOL-MYERS SQUIBB COMPANY;  
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 defendants so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendants shall serve upon Diane M. Coffey, Esquire, plaintiff's attorney, whose address is Lincoln Square, 300 North Market Street, Building One, Suite 204, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendants 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 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*