UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ROY GREEN, on behalf of the Estate of
MARY ANN GREEN, deceased and
ROY GREEN, Individually

CASE NUMBER:

Plaintiffs,

-against-

COMPLAINT AND DEMAND FOR JURY TRIAL

BRISTOL-MYERS SQUIBB AND PFIZER, INC.,

Defendants.

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Plaintiff, ROY HARRIS (hereinafter "Plaintiff"), on behalf of the Estate of MARY ANN GREEN (hereinafter "Plaintiff-decedent"), and ROY GREEN, individually (hereinafter collectively referred to as "Plaintiffs"), by his attorneys, **DOUGLAS & LONDON, P.C. and SCHLICHTER BOGARD & DENTON, LLP,** on behalf of himself individually, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 as Defendants' principal place of business is in this District.

3. This Court has personal jurisdiction over Defendants as their principal headquarters are also in New York. Further, Defendants actively advertise, promote, market, sell, and distribute the drug Eliquis to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff-decedent, MARY ANN GREEN, who used Eliquis, also known as apixaban, approved to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE") in patients who have undergone hip or knee replacement surgery, or for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy.

5. Defendants, BRISTOL-MYERS SQUIBB and PFIZER, INC. (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Eliquis.

6. When warning of safety and risks of Eliquis, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff-decedent and the public in general, that Eliquis had been adequately tested and was found to be safe and/or effective for its indicated use.

7. Defendants concealed their knowledge of Eliquis's defects, from Plaintiff-decedent, the FDA, the public in general and/or the medical community specifically.

8. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff-decedent, 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 community in particular, to recommend, dispense and/or purchase Eliquis for use to reduce the risk of stroke and

systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff-decedent herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Eliquis during clinical trials, forcing Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other treatments to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation and for DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Eliquis whatsoever.

10. As a result of the foregoing acts and omissions, the Plaintiff-decedent was and still is caused to suffer serious and dangerous side effects including inter alia 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Plaintiff-decedent herein has sustained certain of the above health consequences due to Plaintiff-decedent's use of Eliquis.

11. Defendants concealed their knowledge of the defects in their products from the Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, pharmacists, the FDA, and the public in general.

12. Consequently, Plaintiff-decedent seeks compensatory damages as a result of Plaintiff-decedent's use of the Eliquis, which has caused Plaintiff-decedent to suffer from 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, as well as the need for lifelong medical

treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

13. Plaintiff, ROY GREEN, is a citizen of the United States of America, and is a resident of the State of North Carolina.

14. Plaintiff, ROY GREEN, is the spouse of Plaintiff-decedent, MARY ANN GREEN.

15. Plaintiff-decedent, MARY ANN GREEN, was born on May 25, 1947.

16. Plaintiff-decedent, MARY ANN GREEN, first began using Eliquis in or about March 2015, and used Eliquis up through approximately June 2015.

17. As result of using Defendants' Eliquis, Plaintiff-decedent MARY ANN GREEN, was caused to suffer from life-threatening bleeding on or about June 22, 2015, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

18. As a result of the foregoing, Plaintiff-decedent MARY ANN GREEN was caused to suffer sudden death on June 25, 2015.

19. The injuries and damages sustained by Plaintiff-decedent, MARY ANN GREEN, were caused by Defendants' Eliquis.

PARTY DEFENDANTS

20. Upon information and belief, Defendant BRISTOL-MYERS SQUIBB (hereinafter referred to as "BMS") is a company organized under the laws of Delaware, with a principal place of business at 345 Park Ave., New York, New York. Defendant BMS is the holder of the approved New Drug Application ("NDA") for Eliquis as well as the supplemental NDA ("sNDA"). As part of its business, BMS is involved in the research, development, sales, and marketing of pharmaceutical products including Eliquis and apixaban.

21. Upon information and belief, Defendant BMS has transacted and conducted business in the State of New York and the State of North Carolina.

22. Upon information and belief, Defendant BMS has derived substantial revenue from good and products used in the State of New York and the State of North Carolina.

23. Upon information and belief, Defendant, BMS, expected or should have expected its acts to have consequence within the United States of America and the State of New York and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of New York and the State of North Carolina, more particularly.

24. Upon information and belief, and 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, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

25. Upon information and belief, Defendant PFIZER, INC. (hereinafter referred to as "PFIZER") is a Delaware corporation, having a principal place of business at 235 E. 42nd Street, New York, New York.

26. As part of its business, PFIZER is involved in the research, development, sales, and marketing of pharmaceutical products including Eliquis and apixaban.

27. Upon information and belief, Defendant PFIZER has transacted and conducted business in the State of New York and the State of North Carolina.

28. Upon information and belief, Defendant PFIZER, has derived substantial revenue from goods and products used in the State of New York and the State of North Carolina.

29. Upon information and belief, Defendant, PFIZER, expected or should have expected its acts to have consequence within the United States of America and the State of New York and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of New York and the State of North Carolina, more particularly.

30. Upon information and belief, and at all relevant times, Defendant PFIZER, 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, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

FACTUAL BACKGROUND

31. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Eliquis and apixaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

32. Upon information and belief, Defendants BMS and PFIZER participated in a global co-development and co-commercialization agreement for Eliquis, which was discovered originally by Defendant BMS.

33. Defendants first received FDA approval for Eliquis, also known as apixaban, on December 28, 2012 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NDA 202155).

34. Defendants then received additional FDA approval for Eliquis for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery on March 13, 2014 (NDA 202155/S-003).

35. Finally, Defendants received additional FDA approval for Eliquis for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy on August 21, 2014 (NDA 202155/S-006).

36. Defendants launched Eliquis in the United States (hereinafter referred to as the "U.S.") in 2012.

37. Eliquis is part of a class of drugs known as the new oral anticoagulants (hereinafter referred to as "NOACs"), and acts as a Factor Xa inhibitor. It is available by prescription in oral tablet doses of 2.5mg and 5mg.

38. Approval of Eliquis to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation was based on two clinical trials known as the Apixaban for Reduction In Stroke and Other ThromboembоLic Events in Atrial Fibrillation (ARISTOTLE) trial (hereinafter referred to as "ARISTOTLE") and the Apixaban Versus Acetylsalicylic Acid [ASA] to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or Are Unsuitable For Vitamin K Antagonist Treatment (AVERROES) trial (hereinafter referred to as "AVERROES"). The ARISTOTLE study's findings showed that apixaban was superior to warfarin for the prevention of stroke or systemic embolism in patients with atrial fibrillation, with a lesser risk of bleeding and lower mortality. The AVERROES study was terminated early, but showed that apixaban reduced the risk of stroke or systemic embolism without significantly increasing the risk of bleeding, though there were more instances of major bleeding with apixaban as compared to aspirin. (Granger, C.B., et al. *Apixaban versus Warfarin in Patients with Atrial*

Fibrillation. N.Engl.J.Med. 2011;365:981-992; Connolly, S.J., et al. *Apixaban in Patients with Atrial Fibrillation.* N.Engl.J.Med. 2011;364:806-17.)

39. Approval of Eliquis for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery was based on a series of clinical trials known as the Apixaban Dose Orally vs. Anticoagulation with Enoxaparin (ADVANCE) trials (hereinafter referred to as the "ADVANCE" studies). Notably, in the ADVANCE-1 trial, apixaban failed to achieve non-inferiority as compared to enoxaparin for thromboprophylaxis after knee replacement surgery. The findings of the subsequent ADVANCE-2 and ADVANCE-3 studies showed that apixaban was superior (based on the Defendants' definition) to enoxaparin for thromboprophylaxis after knee and hip replacement surgeries, respectively, accompanied by similar rates of bleeding. However, apixaban was associated with a higher rate of mortality in both studies. (Lassen, M.R., et al. *Apixaban or Enoxaparin for Thromboprophylaxis after Knee Replacement.* N.Engl.J.Med. 2009;361:594-604; Lassen, M.R., et al. *Apixaban versus enoxaparin for thromboprophylaxis after knee replacement (ADVANCE-2): a randomized double-blind trial.* Lancet 2010;375:807-15; Lassen, M.R., et al. *Apixaban versus Enoxaparin for Thromboprophylaxis after Hip Replacement.* N.Engl.J.Med. 2010;363:2487-98.)

40. Approval of Eliquis for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy in the U.S. was based on the clinical trials known as the AMPLIFY and AMPLIFY-EXT studies. The AMPLIFY study found that apixaban was non-inferior to enoxaparin followed by warfarin in treating acute venous thromboembolism and showed a reduced risk of bleeding. The AMPLIFY-EXT study tested Eliquis versus a placebo, and merely determined that Eliquis offered an option for reducing the risk of recurrent venous thromboembolism, with an increased risk of clinically relevant nonmajor bleeding as compared to placebo. (Agnelli, G., et al. *Oral Apixaban for the*

Treatment of Acute Venous Thromboembolism. N.Engl.J.Med. 2013;369:799-808; Agnelli, G., et al. *Apixaban for Extended Treatment of Venous Thromboembolism.* N.Engl.J.Med. 2013;368:699-708.)

41. Defendants use the results of the ARISTOTLE and AVERROES studies, the ADVANCE studies, and the AMPLIFY studies to promote Eliquis in their promotional materials, including the Eliquis website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of mortality, among other serious concerns, including life-threatening and serious bleeding events.

42. Moreover, Defendants fail to mention that approval of apixaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation was delayed due to an FDA investigation regarding the quality of the data in the pivotal clinical trials, specifically related to the fact that a substantial number of patients might have received the wrong treatment. Such major trial errors call into question the validity of the data in the clinical trials supporting the other indications as well.

43. Notably, Defendants attempted to seek approval for an indication in high-risk cardiac patients with acute coronary syndrome, but were forced to discontinue the clinical trial after observing excessive bleeding events with no obvious benefits (*i.e.*, no significant reduction in recurrent ischemic events).

44. Defendants market Eliquis, a NOAC, to patients with atrial fibrillation as a treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Eliquis, "something better than warfarin," namely, that Eliquis does not require routine blood testing, does not limit a patient's diet, and does not require regular dose adjustments.

45. Notably, unlike warfarin, there is also no antidote to Eliquis. Therefore, in the event of hemorrhagic complications, there is no available reversal agent.

46. Further, in its final Summary Review of Eliquis for the atrial fibrillation indication, the FDA reviewers noted that there was, "no substantial advantage of apixaban on ischemic stroke," which stands in stark contrast to Defendants' misleading promotional claims that Eliquis "reduced the risk of stroke better than warfarin."

47. Regarding the much-touted lack of routine monitoring requirement with Eliquis and the NOACs, in recent months the FDA, along with other global regulators, has been investigating the potential to significantly improve the benefit/risk profile of the NOACs, including Eliquis, through therapeutic drug monitoring and dose adjustment.

48. Upon information and belief, Defendants did collect pharmacokinetic and pharmacodynamics data that would benefit the discussion of therapeutic drug monitoring, but have not published and/or shared this information and/or analysis.

49. Similarly, when discussing the NOACs in its QuarterWatch publication for the fourth quarter of the 2014 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, "the risks of bleeding are so high that individualizing the dose – as with warfarin – promises to improve the safety profile of this risky class of drugs."

50. As of the fourth quarter of 2014, there were 1,014 Eliquis-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including 492 hemorrhagic events and at least 108 deaths. Further, in terms of the percentage of deaths and total SAEs involving hemorrhage, the difference was quite small between those reported for apixaban and rivaroxaban, which had the highest number of adverse events directly reported to the FDA out of all the drugs on the market at that time.

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

52. Defendants spent significant money in promoting Eliquis, which included at least $8,000,000.00 spent during 2013 alone on physicians, the second most of any drug that year, according to the New York Times.

53. As a result of Defendants' aggressive marketing efforts, U.S. cardiologists prescribed Eliquis more than any other NOAC for patients new to oral anticoagulants in 2014 and 2015. By the fourth quarter of 2014, over 600,000 Eliquis prescriptions had been dispensed for over 230,000 person-years. In addition, the drugs' global sales increased by $628,000,000.00 in 2014, and brought in $1,900,000,000.00 in global annuals sales in 2015. Then, in 2015, sales for Eliquis increased even further to more than clear the $1,000,000,000.00 threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2,000,000,000.00 for the fiscal year.

54. As part of their marketing of Eliquis, Defendants widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiff-decedent, to make inquiries to their prescribing physician about Eliquis and/or request prescriptions for Eliquis.

55. 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 could have permanently disabling, life-threatening and fatal consequences.

56. Prior to Plaintiff-decedent's prescription of Eliquis, Plaintiff-decedent became aware of the promotional materials described herein.

57. Prior to Plaintiff-decedent's prescription of Eliquis, Plaintiff-decedent's prescribing physician received promotional materials and information from sales representatives of Defendants that Eliquis was more effective than warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as treating acute DVT/PE, and/or preventing DVT/PE in patients with prior history of

DVT/PE or undergoing hip or knee replacement surgery, 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.

58. At all times relevant hereto, Defendants also failed to adequately 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.

59. At all times relevant to this action, The Eliquis Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Eliquis has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Eliquis and that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

60. Defendants' original and in some respects current 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 adequately advise prescribing physicians, such as the Plaintiff-decedent's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Eliquis;

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

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

g. failed to include a "**Bolded Warning**" about serious bleeding events associated with Eliquis; and

h. 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.

61. During the years since first marketing Eliquis in the U.S., Defendants modified the U.S. labeling and prescribing information for Eliquis. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Eliquis; and (2) 1,014 SAE Medwatch reports filed with the FDA in 2014 alone, including at least 108 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in the paragraphs above.

62. Prior to applying for and obtaining approval of Eliquis, Defendants knew or should have known that consumption of Eliquis was associated with and/or would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

63. Upon information and belief, despite life-threatening bleeding findings in clinical trials and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Eliquis prior to filing their New Drug Application for Eliquis.

64. Upon information and belief, from the date Defendants received FDA approval to market Eliquis, Defendants made, distributed, marketed, and sold Eliquis without adequate warning to Plaintiff-decedent's prescribing physicians or Plaintiff-decedent that Eliquis was associated with and/or 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.

65. 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.

66. Upon information and belief, Defendants ignored the association between the use of Eliquis and the risk of developing life-threatening bleeding.

67. 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.

68. By reason of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer from 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

69. Plaintiffs have endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff-decedent has suffered serious and dangerous side effects including, inter alia life threatening bleeding and sudden death, 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 premature death.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

70. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

71. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or 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.

72. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or 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, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

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

(b) Manufacturing, producing, promoting, formulating, creating, and/or 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-decedent, 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/or 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, prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and for treatment of acute DVT and/or PE and reducing the risk of recurrence of DVT and/or PE;

(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-decedent in knowing that Eliquis was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff-decedent, healthcare professionals, and/or 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, prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and for treatment of acute DVT and/or PE and reducing the risk of recurrence of DVT and/or PE.

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

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

76. 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 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy;

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

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

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

(e) Failed to warn Plaintiff-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 Plaintiff-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) Were otherwise careless and/or negligent.

77. 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/or sell Eliquis to consumers, including the Plaintiff-decedent.

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

79. Defendants' negligence was the proximate cause of Plaintiff-decedent's injuries, harm and economic loss which Plaintiff-decedent suffered and/or will continue to suffer.

80. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

81. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

82. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

83. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

84. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or 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-decedent.

85. 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.

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

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

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

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

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

91. At the time of the Plaintiff-decedent's use of Eliquis, Eliquis was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have

undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

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

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

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

95. 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.

96. The Eliquis 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.

97. 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-decedent in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff-decedent.

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

99. The Eliquis 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.

100. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

101. The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or 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/or promote their product, Eliquis.

102. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff-decedent for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Eliquis.

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

104. That said defects in Defendants' drug Eliquis were a substantial factor in causing Plaintiff-decedent's injuries.

105. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

106. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

107. By reason of the foregoing, Plaintiff s have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

108. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

111. Plaintiff-decedent did rely on the express warranties of the Defendants herein.

112. 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/or dispensing Eliquis.

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

114. Defendants expressly represented to Plaintiff-decedent, her physicians, healthcare providers, and/or 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 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee

replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

115. 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.

116. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

117. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

118. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

119. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

120. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Eliquis and/or 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, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

121. At the time Defendants marketed, sold, and distributed Eliquis for use by Plaintiff-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.

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

123. 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.

124. Plaintiff-decedent, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

125. Plaintiff-decedent and Plaintiff-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.

126. Eliquis was injected 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.

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

128. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

129. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

130. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

131. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

132. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff-decedent, and/or the FDA, and the public in general, that said product, Eliquis, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

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

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

135. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff-decedent, 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/or purchase said product, Eliquis, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff-decedent herein.

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

137. In reliance upon said representations, the Plaintiff-decedent was induced to and did use Eliquis, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

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

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

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

141. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

142. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

143. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

144. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

147. In representations to Plaintiff-decedent, and/or Plaintiff-decedent's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Eliquis was not as safe as other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy;

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

and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy;

(c) that the risks of adverse events with Eliquis were not adequately tested and/or 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 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy;

(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 and significant rate than other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy;

(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.

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

149. 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-decedent, in particular.

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

151. Defendants knew that Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, healthcare providers, and/or 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.

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

153. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

154. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

155. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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

156. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

157. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff-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 atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

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

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

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

161. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

162. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

163. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

164. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. Defendants conducted research and used Eliquis as part of their research.

166. 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-decedent, Plaintiff-decedent's doctors, hospitals, healthcare professionals, and/or 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, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

167. 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/or the FDA, including the Plaintiff-decedent.

168. 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-decedent, as well as Plaintiff-decedent's respective healthcare providers and/or the FDA.

169. The information distributed to the public, the FDA, and the Plaintiff-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/or omissions.

170. The information distributed to the public, the FDA, and the Plaintiff-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/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

171. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included representations that Defendants' drug Eliquis carried the same risks, hazards, and/or dangers as other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

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

173. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included false representations that Eliquis was as potentially injurious to the health and/or safety of its intended as other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients

who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

174. These representations were all false and misleading.

175. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Eliquis was not safe as a means of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy, and/or was not as safe as other means of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

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

177. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff-decedent, regarding the safety of Eliquis, specifically but not limited to Eliquis being a safe means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

178. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff-decedent, to gain the confidence of the public, healthcare

professionals, the FDA, and/or the Plaintiff-decedent, to falsely ensure the quality and fitness for use of Eliquis and induce the public, and/or the Plaintiff-decedent to purchase, request, dispense, prescribe, recommend, and/or continue to use Eliquis.

179. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Eliquis was fit and safe for use as treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

180. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Eliquis was fit and safe for use as treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy, and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

181. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff-decedent that Eliquis did not present serious health and/or safety risks.

182. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff-decedent that Eliquis did not present health and/or safety risks greater than other oral forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

183. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

184. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff-decedent, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff-decedent and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff-decedent to purchase, use, rely on, request, dispense, recommend, and/or prescribe Eliquis.

185. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Eliquis to the public at large, the Plaintiff-decedent in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy.

186. That 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/or safety concerns of Eliquis.

187. That 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-decedent, as well as her respective healthcare professionals into a sense of security so that Plaintiff-decedent would rely on the representations and purchase, use and rely on Eliquis and/or that Plaintiff-decedent's respective healthcare providers would dispense, prescribe, and/or recommend the same.

188. 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-decedent, as well as Plaintiff-decedent's respective healthcare professionals would rely upon the information being disseminated.

189. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Eliquis.

190. That the Plaintiff-decedent and/or her 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 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for the prophylaxis of DVT and PE in patients who have undergone hip or knee replacement surgery, and/or for the treatment of DVT and PE and the reduction in the risk of recurrent DVT and PE following initial therapy, and were thereby induced to purchase, use and rely on Defendants' drug Eliquis.

191. That at the time the representations were made, the Plaintiff-decedent and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Eliquis.

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

193. That had the Plaintiff-decedent known the true facts with respect to the dangerous and serious health and/or safety concerns of Eliquis, Plaintiff-decedent would not have purchased, used and/or relied on Defendants' drug Eliquis.

194. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff-decedent.

195. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, 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 premature death.

196. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

197. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (WRONGFUL DEATH)

198. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

199. As a result of the foregoing, on June 25, 2015 Plaintiff-decedent, MARY ANN GREEN died from complications proximately related to the Defendant's Eliquis.

200. Plaintiff-decedent, MARY ANN GREEN, left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedents' death have suffered a pecuniary and/or non-pecuniary loss including, but not limited to support, income, services and guidance of the Plaintiff-decedent, MARY ANN GREEN, and were all permanently damaged thereby.

201. At all times herein mentioned, the actions of the named Defendants and their agents, servants, and/or employees, were wanton, grossly negligent, reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the general public and to the decedent in particular.

202. As a result Plaintiff-decedent's estate has been damaged in the sum of TEN MILLION DOLLARS ($10,000,000.00) and punitive damages.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff-decedent, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff-decedent in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

Dated: New York, New York
April 7, 2017

DOUGLAS & LONDON, P.C.

By: _____

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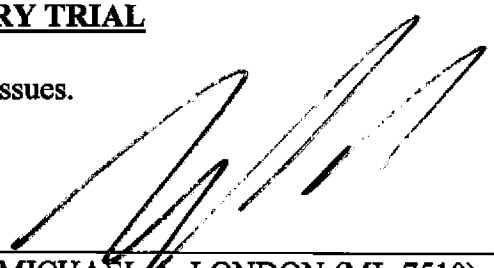
DEMAND FOR JURY TRIAL

Plaintiff hereby demand trial by jury as to all issues.



MICHAELA. LONDON (ML-7510)