UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	)	MDL 2592
	)	SECTION L
	)	JUDGE ELDON E. FALLON
TERRIE TOUPS, DUANE ROCHELLE and PATTY BURAS, individually, and o/b/o THE ESTATE OF FLORENCE BOURGEOIS	)	MAG. JUDGE NORTH
Plaintiffs,	)	
vs.	)	
JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG	)	**COMPLAINT and JURY DEMAND**
	)	Civil Action No.: _____
Defendants	)	

Plaintiffs, by and through the undersigned counsel, 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 Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants' conduct substantial business in this District.

3. Venue is proper in the Eastern District of Louisiana pursuant to Pre-Trial Order No. 9 issued in MDL No. 2592 In re: Xarelto (Rivaroxaban) Products Liability Litigation on March 24, 2015.

NATURE OF THE CASE

4. This action is brought on behalf of TERRIE TOUPS, DUANE ROCHELLE, AND PATTY BURAS, INDIVIDUALLY AND O/B/O THE ESTATE OF FLORENCE BOURGEOIS ("Plaintiffs"). Decedent used Xarelto, also known as rivaroxaban, which is a medication used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "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.

5. Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA

INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

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

7. Defendants concealed their knowledge of Xarelto's defects, from 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 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 Xarelto for use 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, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Decedent herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Decedent, and Decedent's physicians,

hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

10. As a result of the foregoing acts and omissions, the Decedent was caused to suffer serious and dangerous side effects including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death on January 14, 2016, as well as other severe and personal injuries, physical pain and mental anguish. Decedent herein sustained the above injuries, at least in part, due to Decedent's use of Xarelto. Decedent's death or diminished chance of survival was a proximate result of Defendants' tortious acts and omissions as set forth herein.

11. Consequently, Plaintiffs seek compensatory damages as a result of Decedent's use of Xarelto, which has caused Decedent to suffer from bleeding, anemia, urinary tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical pain and mental anguish, as well as the need for medical treatment, follow-up care, and/or medications.

PARTY PLAINTIFF

12. Plaintiffs, as well as Decedent, at all times relevant hereto, are citizens and residents of the State of Louisiana.

13. Decedent was prescribed Xarelto in the State of Louisiana, in or around September 23, 2013, upon direction of Decedent's physician for the treatment of Atrial Fibrillation.

14. Decedent began using Xarelto in or around September 23, 2013, up until approximately January 12, 2016.

15. Upon information and belief, and as a direct and proximate result of the use of Defendants' Xarelto, Decedent experienced urinary bleeding, anemia, urinary tract infection, sepsis and kidney failure from the use of Xarelto, and died on January 14, 2016 from septic shock.

16. As a direct and proximate result of the use of Defendants' Xarelto, Decedent suffered serious and dangerous side effects including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death on January 14, 2016, as well as other severe and personal injuries, physical pain and mental anguish.

17. As a direct and proximate result of Defendants' conduct, Decedent suffered and incurred damages, including medical expenses and other economic and non-economic damages.

PARTY DEFENDANTS

18. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D's sole member is Janssen Pharmaceuticals, Inc., which is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Accordingly, JANSSEN R&D is a citizen of Pennsylvania and New Jersey for purposes of determining diversity under 28 U.S.C. § 1332.

19. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

20. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

21. Upon information and belief, Defendant JANSSEN R&D has transacted and conducted business in the State of Louisiana.

22. Upon information and belief, Defendant JANSSEN R&D has derived substantial revenue from good and products used in the State of Louisiana.

23. Upon information and belief, Defendant, JANSSEN R&D, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

24. Upon information and belief, and at all relevant times, Defendant, JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with nonvalvular 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.

25. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

26. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

27. Upon information and belief, Defendant, JANSSEN PHARM has transacted and conducted business in the State of Louisiana.

28. Upon information and belief, Defendant, JANSSEN PHARM, has derived substantial revenue from goods and products used in the State of Louisiana.

29. Upon information and belief, Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

30. Upon information and belief, and at all relevant times, Defendant, JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with nonvalvular 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.

31. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated in Ireland with

a principal place of business in Puerto Rico. Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland and Puerto Rico for purposes of determining diversity under 28 U.S.C. § 1332.

32. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

33. Upon information and belief, Defendant, JANSSEN ORTHO has transacted and conducted business in the State of Louisiana.

34. Upon information and belief, Defendant, JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of Louisiana.

35. Upon information and belief, Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

36. Upon information and belief, and at all relevant times, Defendant, JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with nonvalvular 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.

37. Upon information and belief, Defendant JOHNSON & JOHNSON (hereinafter referred to as "J&J) is a corporation organized under the laws of New Jersey with its principal

place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

38. As a part of its business, Defendant J&J is and at all relevant times was, involved in the research, development, packaging, labeling, sales, and/or marketing of pharmaceutical products including Xarelto. Defendant J&J manufactures, markets and sells a wide range of pharmaceutical products including Xarelto (rivaroxaban).

39. Upon information and belief, Defendant J&J has transacted and conducted business in the State of Louisiana.

40. Upon information and belief, Defendant J&J has derived substantial revenue from goods and products used in the State of Louisiana.

41. Upon information and belief, Defendant J&J expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

42. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

43. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

44. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

45. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has transacted and conducted business in the State of Louisiana.

46. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of Louisiana.

47. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

48. Upon information and belief, and at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto 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, 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.

49. Upon information and belief, Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

50. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

51. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

52. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

53. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

54. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of Louisiana.

55. Upon information and belief, Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of Louisiana.

56. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

57. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto 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, 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.

58. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

59. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

60. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

61. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Louisiana, by selling and distributing its products in the State of Louisiana, and engaged in substantial commerce and business activity in the State of Louisiana.

62. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey. BAYER HEALTHCARE LLC's sole member is Bayer Corporation, and is wholly owned by Bayer

Corporation, which is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Accordingly, BAYER HEALTHCARE LLC is a citizen of Delaware, New Jersey, Indiana and Pennsylvania for purposes of determining diversity under 28 U.S.C. § 1332.

63. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Louisiana, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC.

64. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America and in the State of Louisiana, and derived substantial revenue from interstate commerce.

65. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto 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, 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.

66. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER

CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMA AG.

67. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Louisiana, and derived substantial revenue from interstate commerce.

68. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Louisiana, and derived substantial revenue from interstate commerce.

69. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

70. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

71. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

72. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

73. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Louisiana, and derived substantial revenue from interstate commerce.

74. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Louisiana, and derived substantial revenue from interstate commerce.

75. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto 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, 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.

FACTUAL BACKGROUND

76. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto and rivaroxaban 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.

77. Defendants received FDA approval for Xarelto, also known as rivaroxaban, on or about July 1, 2011 for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries (NDA 022406).

78. Defendants then received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on or about November 4, 2011 (NDA 202439).

79. The additional indication for treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE was added to the label on or about November 2, 2012.

80. Defendants launched Xarelto in the United States (hereinafter referred to as the "U.S.") in or about 2011.

81. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, and 10mg.

82. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), accompanied by similar rates of bleeding. However, the studies also showed a greater incidence with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty*. N.Engl.J.Med. 2008;358:2776-86; Kakkar, A.K., et al. *Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial*. Lancet 2008;372:31-39; Ericksson, B.I., et al. *Rivaroxaban*

versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. N.Engl.J.Med. 2008;358:2765-75.).

83. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF"). The study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. *Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation*. N.Engl.J.Med. 2011;365:883-91.).

84. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism*. N.Engl.J.Med. 2010;363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. *Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study*

(EINSTEIN-Extension study). Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEINPE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N.Engl.J.Med. 2012;366:1287-97.).

85. Defendants used the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

86. Defendants marketed Xarelto as a new oral anticoagulant 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 Xarelto over warfarin, which they refer to as the Xarelto Difference – namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet.

87. However, in its QuarterWatch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto],

saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing."

88. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

89. Defendants spent significant money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

90. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately $582 million in sales globally.

91. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto. In the U.S., approximately 1 million Xarelto prescriptions had been written by the end of 2013.

92. During the Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

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

94. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Xarelto 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 Xarelto, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

95. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

96. Prior to Decedent's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or after 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 Xarelto.

97. At all times relevant hereto, Defendants also failed to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

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

99. In the year leading up to or about June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

100. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

101. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

102. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

103. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related averse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

104. 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 Xarelto.

105. Defendants original, and in some respects current labeling and prescribing information for Xarelto:

(a) failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;

(b) failed to provide adequate warnings about the true safety risks associated with the use of Xarelto;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto 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/or extent of anticoagulation in patients taking Xarelto;

(e) failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;

(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 Xarelto;

(g) failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

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

(i) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

(j) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;

(k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;

(l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;

(m) failed to include a "**BOXED WARNING**" about serious bleeding events associated with Xarelto;

(n) failed to include a "**BOLDED WARNING**" about serious bleeding events associated with Xarelto; and

(o) in their "Medication Guide" intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

106. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1)

serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 106 (a – o).

107. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, anemia, urinary tract infection, sepsis, kidney failure and death, 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.

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

109. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Decedent's prescribing physicians or Decedent that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding, anemia, urinary tract infection, sepsis and death in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding or the consequences thereof, particularly in elderly women, who are at increased risk from such adverse effects of the drug.

110. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study the above risks.

111. Upon information and belief, Defendants ignored the association between the use of Xarelto and the serious and life-threatening risks associated with its use.

112. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for the above risks further rendered warnings for this medication inadequate.

113. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for the above risks was a proximate cause of prescribing physicians failure to use due care in prescribing Xarelto, compromised the informed consent requirements due patients like Decedent and precludes application of the learned intermediary doctrine. By Defendants.

114. By reason of the foregoing acts and omissions, the Decedent was caused to suffer the damages listed herein.

115. By reason of the foregoing acts and omissions, Decedent endured physical pain and suffering, emotional and mental anguish and medical and funeral expenses as a result of the actions and inactions of the Defendants.

PLAINTIFFS' CLAIMS

116. Defendants are strictly liable to Plaintiffs for the wrongful death of their mother, the Decedent, and are further liable for negligence and want of reasonable care in designing,

researching, the application for FDA approval, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

117. Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries experienced by Decedent

118. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto.

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

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

(a) Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto 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/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

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

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

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

(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 Xarelto;

(g) Failed to warn Decedent, prior to actively encouraging the sale of Xarelto, 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.

121. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Xarelto to consumers, including Decedent.

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

123. Defendants' negligence was the proximate cause of Decedent's injuries and death.

124. As a result of the foregoing acts and omissions, Decedent was caused to suffer serious and dangerous side effects, including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical

pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

125. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including the death of their mother and other damages to which they are entitled.

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

127. Xarelto was unreasonably dangerous in it normal and anticipated use in patients generally and Decedent in particular.

128. 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 Xarelto as hereinabove described that was used by the Decedent.

129. Defendants' Xarelto 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.

130. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Decedent herein.

131. The Xarelto 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 Xarelto.

132. The Xarelto 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.

133. At all times herein mentioned, Xarelto was in a defective condition and unsafe, especially when used in the form and manner as provided by the Defendants.

134. At the time of the Decedent's use of Xarelto, Xarelto 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, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

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

137. The Xarelto 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' Xarelto was manufactured.

138. 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 Plaintiffs and Decedent.

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

140. The Xarelto 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 and the Defendants failed to adequately warn of said risks.

145. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Xarelto.

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

147. Said defects in Defendants' drug Xarelto were a substantial factor in causing Decedent's injuries.

148. As a result of the foregoing acts and omissions, Decedent was caused to suffer serious and dangerous side effects, including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

149. Defendants expressly warranted that Xarelto was safe and well accepted by users.

150. Xarelto does not conform to these express representations because Xarelto 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, Plaintiffs suffered the loss of their mother (Decedent).

151. Decedent and her primary physician did rely on the express warranties of the Defendants herein.

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

153. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

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

155. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto 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.

156. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, 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.

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

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

159. Said representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

160. 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.

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

162. Xarelto 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.

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

164. The Defendants negligently and or intentionally falsely and fraudulently represented to the medical and healthcare community, and to the Decedent, and/or the FDA, and the public in general, that said product, Xarelto, 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, 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.

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

166. 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.

167. These representations were made by said Defendants as a result of gross negligence, wanton lack of care and/or with the intent of defrauding and deceiving the 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, Xarelto, 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/or 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.

168. At the time the aforesaid representations were made by the Defendants and, at the time the Decedent used Xarelto, the Decedent and her doctors were unaware of the falsity of said representations and reasonably believed them to be true.

169. In reliance upon said representations, Decedent and her doctors were induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries, and, ultimately, death.

170. Defendants knew or should have known that Xarelto 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.

171. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of Decedent.

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

173. Defendants knew or were reckless in not knowing that their representations were false.

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

175. 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 Xarelto, including the Decedent, in particular.

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

177. Defendants knew that Decedent, and her 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 Xarelto, as set forth herein.

178. Decedent, as well as 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.

179. As a result of the foregoing acts and omissions, Decedent was caused to suffer serious and dangerous side effects, including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

180. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including the death of their mother and other damages to which they are entitled.

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

182. 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/or the FDA that Xarelto 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/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

183. 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 Decedent.

184. 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 Plaintiff's respective healthcare providers and/or the FDA.

185. 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/or omissions.

186. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included representations that Defendants' drug Xarelto 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.

187. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and/or 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/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

189. The information distributed to the public, the FDA, and the Decedent, by Defendants intentionally included false representations that Xarelto was as potentially injurious to the health and/or 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/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

190. These representations were false and misleading.

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

192. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto.

193. 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 Decedent, as well as Decedent's 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 Xarelto and/or that Decedent's respective healthcare providers would dispense, prescribe, and/or recommend the same.

194. Decedent and/or 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/or 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 Xarelto.

195. Had the Decedent or her health care providers known the true facts with respect to the dangerous and serious health and/or safety concerns of Xarelto, Decedent would not have purchased, used and/or relied on Defendants' drug Xarelto.

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

196. As a result of the foregoing acts and omissions, Decedent was caused to suffer serious and dangerous side effects, including inter alia life-threatening bleeding, anemia, urinary tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical

pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

197. As a result of the foregoing acts and omissions, Plaintiffs have suffered and incurred damages, including the death of their mother and other damages to which they are entitled.

198. Defendants have a statutory duty to refrain from making false or fraudulent representations and/or from engaging in deceptive acts or practices in the sale and promotion of Xarelto pursuant to the Louisiana Unfair Trade Practices Act, which prohibits and declares such acts or practices as unlawful.

199. Defendants engaged in unfair, deceptive, false and/or fraudulent acts and/or practices in violation of the Act through its false and misleading promotion of Xarelto designed to induce Decedent to purchase and use Xarelto.

200. 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.

201. Defendants misrepresented the alleged benefits of Xarelto, failed to disclose material information concerning known side effects of Xarelto, misrepresented the quality of

Xarelto, and otherwise engaged in fraudulent and deceptive conduct which induced Decedent to purchase and use Xarelto.

202. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side-effects related to the use of Xarelto, 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.

203. Defendants' conduct in connection with Xarelto 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 Xarelto.

204. Defendants' conduct as described above was a material cause of Decedent's purchase of Xarelto.

205. Despite Defendants' knowledge of Xarelto's defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as maximize sales and profits at the expense of the health and safety of the public, including the Decedent, in conscious disregard of the foreseeable harm caused by Xarelto.

206. Defendants' conduct was intentional and/or wanton.

207. As a result of the foregoing acts and omissions, Decedent was caused to suffer serious and dangerous side effects, including inter alia life-threatening bleeding, anemia, urinary

tract infection, sepsis, renal failure and death, as well as other severe and personal injuries, physical pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

208. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein, including the death of their mother and other damages pecuniary and non-pecuniary alike to which they are entitled.

RELIEF SOUGHT

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to, wrongful death damages and survival action damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical and funeral expenses in an amount to be determined at trial of this action;

3. 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 in an amount sufficient to punish Defendants and deter future similar conduct;

4. Pre-judgment interest;

5. Post-judgment interest;

6. Awarding Plaintiffs reasonable attorneys' fees;

7. Awarding Plaintiffs the costs of these proceedings; and

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

Plaintiffs hereby demand trial by jury as to all issues.

Dated: January 17, 2017

Respectfully Submitted,

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