**IN THE UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

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| JOSEPH J. BOUDREAUX, JR. and LORETTA BOUDREAUX, | * | |
| Plaintiffs, | * | |
| v. | * | **CASE NUMBER:** |
| 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., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER HEALTHCARE AG, and BAYER AG, | * | **JUDGE:** |
| | * | **MAGISTRATE:** |
| | * | **JURY DEMAND** |
| Defendants | * | |

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The Plaintiffs, Joseph J. Boudreaux, Jr. and Loretta Boudreaux, competent individuals, by and through the undersigned counsel, upon information and belief at all times hereinafter aforementioned, 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 the Defendants conduct substantial business in this District.

3. This Court has personal jurisdiction over the Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, have substantial and continuing contact with the State of Louisiana, and derive substantial revenue from goods used and consumed within the State of Louisiana. The Defendants actively sell, market and promote their pharmaceutical product, Xarelto, to physicians and consumers in this state on a regular and consistent basis.

## NATURE OF THE CASE

4. This action is brought for the Plaintiff, Joseph J. Boudreaux, Jr., who was prescribed and started taking Xarelto for his atrial fibrillation ("AFib") on or about January 13, 2014 upon direction of the Plaintiff's physician. As a result of Xarelto, the Plaintiff, Joseph J. Boudreaux, Jr., suffered a severe gastrointestinal bleed for which he had to undergo blood transfusions.

5. The 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., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "the Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed Xarelto.

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

7. The Defendants concealed their knowledge of Xarelto's defects from the Plaintiffs and the Plaintiff's physicians, the FDA, the public in general and/or the medical community specifically.

8. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiffs, 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 Plaintiff herein.

9. The Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing the Plaintiffs, and the Plaintiff'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. The Defendants concealed their knowledge of the defects in Xarelto from the Plaintiffs, and the Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

11. As a direct and proximate cause of the Defendants' aforesaid actions and the Plaintiff's reasonably anticipated use of Xarelto, the Plaintiffs suffered serious and dangerous side effects including a serious gastrointestinal bleed requiring hospitalization, as well as other severe and personal injuries which were permanent and lasting in nature, including but not limited to physical pain and mental anguish, expenses for medical treatment and hospitalization, diminished enjoyment of life, loss of consortium, lost wages and any and all damages that are reasonable in the premises. The Plaintiff herein has sustained the above health consequences due to the Plaintiff's use of Xarelto.

**THE PARTY PLAINTIFF**

12. The Plaintiff, Joseph J. Boudreaux, Jr., at all times relevant hereto, is a citizen and resident of Lafourche Parish, State of Louisiana, who, upon information and belief, suffered personal injuries, as a result of his use of Xarelto.

13. Upon information and belief, the Plaintiff was prescribed Xarelto for his AFib in Lafourche Parish, State of Louisiana, on or about January 9, 2014, upon the direction of his physician.

14. Upon information and belief, the Plaintiff first began using Xarelto on January 13, 2014 and used it through February 3, 2014. The Plaintiff was hospitalized on February 3, 2014 for a severe gastrointestinal bleed, dizziness, weakness and fatigue accompanied by black, tarry stools. He was diagnosed with a gastrointestinal bleed, and he had to endure several blood transfusions.

15. Upon information and belief, as a direct and proximate result of the use of the Defendants' Xarelto, the Plaintiff experienced a severe gastrointestinal bleed for which he was hospitalized on February 3, 2014 at St. Anne Hospital in Raceland, Louisiana. He was transferred to Ochsner Medical Center in Kenner, Louisiana, where he remained under treatment until February 7, 2014. Due to his injuries, he required follow-up medical treatment.

16. As a direct and proximate result of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including a severe gastrointestinal bleed, as well as other severe and personal injuries which were permanent and lasting in nature, including, but not limited to, physical and mental pain and suffering, expenses for hospitalization and medical treatment, diminished enjoyment of life, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

**PARTY DEFENDANTS**

17. Upon information and belief, the Defendant, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTCAL 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 in New Jersey. The Defendant JANSSEN R&D submitted the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDAs.

18. As part of its business, JANSSEN R&D is involved in the research, testing and development, and on information and belief, indirectly in the sales, and/or marketing of pharmaceutical products including Xarelto and rivaroxaban.

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

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

21. Upon information and belief, the 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 it derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

22. Upon information and belief, and at all relevant times, the Defendant, JANSSEN R&D, was in the business of and did test, research, and develop, and on information and belief, did directly or indirectly participate in the design, manufacture, advertising, promotion, marketing, sale, and/or distribution of 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.

23. Upon information and belief, the 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 its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

24. As part of its business, Xarelto is JANSSEN PHARM's product, and thus JANSSEN PHARM was directly or indirectly involved in the research, development, sales, manufacturing and/or marketing of pharmaceutical products including Xarelto and rivaroxaban.

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

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

27. Upon information and belief, the 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 the Defendant, JANSSEN PHARM derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

28. Upon information and belief, and at all relevant times, the Defendant, JANSSEN PHARM, was in the business of and did directly or indirectly design, research, manufacture, test, advertise, promote, market, sell, and/or distribute its 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.

29. Upon information and belief, the 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.

30. As part of its business, JANSSEN ORTHO manufactured the finished Xarelto product and is directly or indirectly involved in the research, development, manufacturing, sales, and/or marketing of pharmaceutical products including Xarelto and rivaroxaban.

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

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

33. Upon information and belief, the 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.

34. Upon information and belief, and at all relevant times, the Defendant, JANSSEN ORTHO, was in the business of and did manufacture the finished product, Xarelto, and did directly or indirectly design, research, test, advertise, promote, market, sell, and/or 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.

35. Upon information and belief, the 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 New Jersey.

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

37. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the promotion, and, on information and belief, directly or indirectly in the research, development, sales and/or marketing of pharmaceutical products including Xarelto and rivaroxaban.

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

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

40. Upon information and belief, the 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.

41. Upon information and belief and at all relevant times, the Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did promote and, on information and belief, directly or indirectly did participate in the design, research, manufacture, testing, advertising, promotion, marketing, sale, and/or distribution of 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 therapy.

42. Upon information and belief, the Defendant, BAYER PHARMA AG, is a German pharmaceutical company with its principal place of business in Germany.

43. The 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.

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

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

46. As part of its business, BAYER PHARMA AG is and/or was involved in the design, research, testing and development, and on information and belief, was directly or indirectly involved in the sales and/or marketing of pharmaceutical products including Xarelto and rivaroxaban.

47. Upon information and belief, the Defendant, BAYER PHARMA AG, has directly and/or indirectly transacted and conducted business in the State of Louisiana.

48. Upon information and belief, the Defendant, BAYER PHARMA AG, has directly and/or indirectly derived substantial revenue from goods and products used in the State of Louisiana.

49. Upon information and belief, the 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 directly and/or indirectly substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

50. Upon information and belief, and at all relevant times, the Defendant, BAYER PHARMA AG, was in the business of and did design, research, test, and develop, and, on information and belief, directly or indirectly did advertise, promote, market, sell, and/or

distribute the drug Xarelto for use as an oral anticoagulant and factor Xa inhibitor, 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.

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

52. Upon information and belief, the Defendant, BAYER CORPORATION, is the sole member of the Defendant, BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc. which owns 100% of all of the issued and outstanding shares of the common stock of the Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, the Defendant, BAYER CORPORATION, is the parent of the Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC.

53. At relevant times, the Defendant, BAYER CORPORATION, was engaged directly or indirectly 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.

54. At relevant times, the Defendant BAYER CORPORATION conducted regular and sustained business, directly or indirectly, 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.

55. Upon information and belief, the 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 New Jersey.

56. Upon information and belief, at all relevant times, the Defendant, BAYER HEALTHCARE LLC, has transacted and conducted business, directly or indirectly, in the State of Louisiana, and derived substantial revenue from interstate commerce. The Defendant, BAYER CORPORATION, is the sole member of the Defendant, BAYER HEALTHCARE, LLC. BAYER HEALTHCARE, LLC owns Schering Berlin, Inc. which owns all of the issued and outstanding common stock of the Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC.

57. Upon information and belief, at all relevant times, the 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.

58. Upon information and belief, at all relevant times, the Defendant, BAYER HEALTHCARE LLC, was in the business of and did, directly and/or indirectly, design, research, manufacture, test, advertise, promote, market, sell, or 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.

59. Upon information and belief, the Defendant, BAYER HEALTHCARE AG, is a company domiciled with its principal place of business in Germany and is the parent/holding

company of the Defendants, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and/or BAYER PHARMA AG.

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

61. Upon information and belief, at all relevant times, the 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, directly or indirectly, substantial revenue from interstate commerce.

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

63. Upon information and belief, the Defendant, BAYER AG, is a German materials science and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

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

65. Upon information and belief, and at all relevant times, the Defendant, BAYER AG wholly owns the Defendants, BAYER PHARMA AG and BAYER HEALTHCARE AG. BAYER AG also indirectly owns the Defendants, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER CORPORATION, AND BAYER HEALTHCARE, LLC.

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

67. Upon information and belief, at all relevant times, the 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, directly or indirectly, from interstate commerce.

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

69. At all relevant times, the 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.

70. The Defendants, and specifically on information and belief the Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON & JOHNSON

PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, submitted the initial NDA no. 022406 for Xarelto to the FDA in July of 2008.

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

72. The 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 November 4, 2011 (NDA 202439).

73. 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 November 2, 2012.

74. The Defendants launched Xarelto in the United States (hereinafter referred to as the "U.S.") in 2011.

75. 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.

76. 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.)

77. 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 non-inferior 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.)

78. 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 EINSTEIN-PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N.Engl.J.Med. 2012;366:1287-97.

79. The Defendants use 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, the Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

80. The Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, for 60 years. The 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.

81. 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."

82. 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.

83. The 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.

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

85. The 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.

86. 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.

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

88. In the course of these direct to consumer advertisements, the 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.

89. On June 6, 2013, the 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 the Defendants immediately cease distribution of such promotional material.

90. Prior to the Plaintiff's prescription of Xarelto, the Plaintiffs and/or the Plaintiff's physician became aware of the promotional materials described herein.

91. Prior to the Plaintiff's prescription of Xarelto, the Plaintiff's prescribing physician received promotional materials and information from sales representatives of the 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 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.

92. At all times relevant hereto, the 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.

93. At all times relevant to this action, The Xarelto Medication Guide, prepared and distributed by the 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.

94. In the year leading up to 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.

95. 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.

96. 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."

97. 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.

98. 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.

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

100. The 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 disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;

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

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

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

h) 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;

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

j) 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;

k) failed to provide adequate warnings regarding a patient on Xarelto and the risk of developing an epidural or spinal hematoma when neuraxial anesthesia or spinal puncture is employed;

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) failed to disclose to patients in the Defendants' "Medication Guide," intended for distribution to patients to whom Xarelto has been prescribed, 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.

101. During the years since first marketing Xarelto in the U.S., the 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, the Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 100 (a – o).

102. Prior to applying for and obtaining approval of Xarelto, the Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, and the Defendants possessed at least one clinical scientific study, which evidence the 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.

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

104. Upon information and belief, from the date the Defendants received FDA approval to market Xarelto, the Defendants made, distributed, marketed, and sold Xarelto without adequate warning to the Plaintiff's prescribing physicians or to the Plaintiff that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that the Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

105. Upon information and belief, the 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 said risk.

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

107. The Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

108. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding/anemia requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in

nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, lost wages and loss of consortium and any and all damages that are reasonable in the premises.

**FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOUISIANA PRODUCT LIABILITY ACT) La. R.S. 9:2800.51, *et. seq*.**

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

110. The Plaintiffs' injuries and damages were caused by a characteristic of Xarelto that renders the product unreasonably dangerous because the Plaintiffs' injuries and damages arose from a reasonably anticipated use of the product by the Plaintiff, Joseph J. Boudreaux, Jr.

111. That at the time Xarelto left the Defendants' control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the Defendants and as such was unreasonably dangerous in construction or composition.

112. That Xarelto was unreasonably dangerous in design in that at the time when Xarelto left the Defendants' control, there existed an alternative design for the product that was capable of preventing the Plaintiffs' damages, and the likelihood that Xarelto's design would cause the Plaintiffs' injuries and damages and the gravity of those injuries and damages outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

113. That Xarelto had an inadequate warning because at the time it left the Defendants' control, the product possessed a characteristic that may cause damage and the Defendants failed

to use reasonable care to provide an adequate warning of such characteristics and its danger to users and handlers of the product, thereby rendering the product unreasonably dangerous.

114. That the unreasonably dangerous characteristics of Xarelto were beyond that which would be contemplated by the ordinary user such as Joseph J. Boudreaux, Jr. with the ordinary knowledge common to the community as to the product's characteristics.

115. That in the alternative, the Defendants, after Xarelto left their control, acquired knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or they would have acquired such knowledge had they acted as a reasonably prudent manufacturer, and therefore the Defendants are liable unto the Plaintiffs as a result of their subsequent failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to users of the product, such as Joseph J. Boudreaux, Jr.

116. That Xarelto was unreasonably dangerous because it did not conform to an express warranty made by the Defendants about the product and the express warranty induced the Plaintiff, Joseph J. Boudreaux, Jr., to use the product and the Plaintiffs' damages were proximately caused because the express warranty was untrue.

117. That at the time Xarelto left the Defendants' control, the Defendants, in light of then existing reasonably available scientific and technological knowledge, knew of the design characteristic that caused the damage and the danger of such characteristic.

118. That at the time Xarelto left the Defendants' control, the Defendants, in light of then existing reasonably available scientific and technological knowledge, knew of the existing technologically and economically safer alternative design characteristic than that which caused the damage and the danger of such characteristic.

119. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding/anemia requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

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

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

121. The Defendants had a duty to exercise reasonable care in the designing, researching, 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.

122. The 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 Xarelto into interstate commerce in that the 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 which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life as well as the need for life-long medical treatment, monitoring and or medications.

123. 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 Xarelto without thoroughly testing it;

b) Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without adequately testing it;

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

d) Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;

e) Negligently failing to adequately and correctly warn the Plaintiff, the Plaintiff's physicians, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;

f) Failing to provide adequate instructions regarding safety precautions to be followed by users such as the Plaintiff, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto;

g) Failure to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto;

h) Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities;

i) Negligently representing that Xarelto was safe for use for its intended purpose, when, in fact, it was unsafe;

j) Negligently representing that Xarelto 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, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

k) Negligently designing Xarelto in a manner which was dangerous to its users;

l) Negligently manufacturing Xarelto in a manner which was dangerous to users;

m) Negligently producing Xarelto in a manner which was dangerous to its users;

n) Negligently assembling Xarelto in a manner which was dangerous to its users;

o) Concealing information from the Plaintiffs in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations;

p) Improperly concealing and/or misrepresenting information from the Plaintiffs, the Plaintiff's physicians, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Xarelto compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

q) The Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto;

r) The 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, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

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

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

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

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

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

5. Failed to warn Plaintiffs of the severity and duration of such adverse effects, as the warnings did not accurately reflect the symptoms, or severity of the side effects;

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

7. Failed to warn the Plaintiffs, 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;

8. Were otherwise careless and/or negligent.

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

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

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

127. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

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

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

129. 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 Plaintiff.

130. That 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.

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

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

133. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the 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.

134. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and the 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.

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

136. At the time of the Plaintiff'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/or for prophylaxis of DVT for patients undergoing hip or knee replacement surgery.

137. The Defendants with this knowledge voluntarily designed their Xarelto in a dangerous condition for use by the public, and in particular the Plaintiffs.

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

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

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

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

142. The 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 Plaintiffs in particular, and, the Defendants are therefore strictly liable for the injuries sustained by the Plaintiffs.

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

144. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the 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.

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

146. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after the 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 Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

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

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

149. That said defects in the Defendants' drug Xarelto were a substantial factor in causing the Plaintiffs' injuries.

150. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

**FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF EXPRESS WARRANTY) La. R.S. 9:2800.58**

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

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

153. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous serious side effects, about many of which the Defendants did not accurately warn. As a direct and proximate result of the breach of said warranties, the Plaintiffs suffered severe and permanent personal injuries, harm and economic loss.

154. The Plaintiffs did rely on the express warranties of the Defendants herein.

155. 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.

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

157. The Defendants expressly represented to the Plaintiffs, the Plaintiff'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, for 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.

158. The 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, it produced serious injuries to the users that were not accurately identified and represented by the Defendants.

159. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

**FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF IMPLIED WARRANTIES) La. C.C. art. 2524**

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

161. 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.

162. At the time the Defendants marketed, sold, and distributed Xarelto for use by the Plaintiff, the 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.

163. 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.

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

165. The Plaintiff 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.

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

167. 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, such as the Plaintiff, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

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

169. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

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

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

171. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiffs 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.

172. That representations made by the Defendants were, in fact, false.

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

174. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiffs, 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 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, all of which

evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

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

176. In reliance upon said representations, the Plaintiffs were induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

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

178. The 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.

179. The Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiffs.

180. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

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

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

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

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

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

a) that Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

b) that the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

c) that the risks of adverse events with Xarelto were not adequately tested and/or known by the Defendants;

d) that the Defendants were aware of dangers of Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT

and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

e) that Xarelto 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, at a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

f) that patients had to be monitored more regularly than normal while using Xarelto;

g) that Xarelto was manufactured negligently;

h) that Xarelto was manufactured defectively;

i) that Xarelto was manufactured improperly;

j) that Xarelto was designed negligently;

k) that Xarelto was designed defectively; and

l) that Xarelto was designed improperly.

185. The Defendants were under a duty to disclose to the Plaintiffs and the Plaintiff'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.

186. The 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 Plaintiffs, in particular.

187. The Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of Xarelto, were made purposefully, willfully, wantonly, and/or recklessly, to mislead the Plaintiffs and the Plaintiff'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.

188. The Defendants knew that the Plaintiffs and the Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, including material omissions of facts surrounding Xarelto, as set forth herein.

189. The Plaintiffs, as well as the Plaintiff'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 the Defendants.

190. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

## EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

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

192. The Defendants had a duty to make correct representations to the Plaintiffs, the FDA, the medical community and the public. The Defendants represented to the medical and healthcare community, and to the Plaintiffs, the FDA, and the public in general that said product,

Xarelto, 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, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

193. The representations made by the Defendants were, in fact, false.

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

195. The Defendants breached their duty in representing Xarelto's serious side effects to the medical and healthcare community, to the Plaintiffs, the FDA and the public in general.

196. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding/anemia requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

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

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

198. The Defendants conducted research, or lack thereof, and used Xarelto as part of their research.

199. As a result of the Defendants' research and testing, or lack thereof, the Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiffs, the Plaintiff'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.

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

201. The 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 Plaintiffs, as well as the Plaintiff's respective healthcare providers and/or the FDA.

202. The information distributed to the public, the FDA, the Plaintiffs and the Plaintiff's respective healthcare providers 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.

203. The information distributed to the public, the FDA, the Plaintiffs and the Plaintiff's respective healthcare providers by Defendants intentionally included representations that the 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.

204. The information distributed to the public, the FDA, the Plaintiffs and the Plaintiff's respective healthcare providers by Defendants intentionally included representations that the 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, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

206. The information distributed to the public, the FDA, and the Plaintiffs by the 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, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

207. These representations were all false and misleading.

208. Upon information and belief, the Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants and results that demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of

DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and/or was not as safe as other means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

209. The Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs regarding the safety of Xarelto, specifically including but not limited to Xarelto not having dangerous and serious health and/or safety concerns.

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

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

212. The Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs that Xarelto was fit and safe for use as a treatment for reducing the risk of stroke and systemic

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

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

214. That the Defendants made claims and representations in their documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiffs that Xarelto did not present serious health and/or safety risks.

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

216. That these representations and others made by the 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.

217. That these representations and others made by the Defendants were made with the intention of deceiving and defrauding the Plaintiffs, including the Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiffs and/or the Plaintiff's respective healthcare professionals to rely upon misrepresentations, and they caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Xarelto.

218. That the Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, and the Plaintiffs 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 for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

219. That the 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.

220. That the 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 Plaintiffs, as well as the Plaintiff's healthcare professionals, into a sense of security so that the Plaintiffs would rely on the representations made by the Defendants, and

purchase, use and rely on Xarelto, and/or that the Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

221. The 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 Plaintiffs as well as the Plaintiff's respective healthcare professionals, would rely upon the information being disseminated.

222. The Defendants utilized direct-to-consumer adverting to market, promote, and/or advertise Xarelto.

223. That the Plaintiffs, and/or the Plaintiff's respective healthcare professionals, did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, for 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.

224. That at the time the representations were made, the Plaintiffs, and/or the Plaintiff's respective healthcare providers, did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

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

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

227. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiffs.

228. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiffs suffered serious and dangerous side effects including severe bleeding requiring transfusions, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, loss of consortium, lost wages and any and all damages that are reasonable in the premises.

**TENTH CAUSE OF ACTION: VIOLATION OF UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW § 51:1401, *et seq.***

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

230. The Defendants have a statutory duty to refrain from unfair trade practices in the design, development, manufacture, promotion and sale of Xarelto.

231. Had the Defendants not engaged in the deceptive conduct described herein, the Plaintiffs would not have purchased and/or paid for Xarelto, and would not have incurred related medical costs. Specifically, the Plaintiffs, the Plaintiff's physician, and the Plaintiff's physician's staff were misled by the deceptive conduct described herein.

232. The Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including the Plaintiffs, constituted unfair trade practices in violation of the state consumer protection statute listed above.

233. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from the Plaintiffs for Xarelto that they would not have paid had the Defendants not engaged in unfair trade practices.

234. The Plaintiffs were injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, such as Plaintiffs, physicians and consumers was to create a demand for and sell Xarelto. Each aspect of the Defendants' conduct combined to artificially create sales of Xarelto.

235. The medical community relied upon the Defendants' misrepresentations and omissions in determining to use Xarelto.

236. By reason of wrongful acts engaged in by the Defendants, the Plaintiffs suffered ascertainable loss and damages.

237. As a direct and proximate cause of the Defendants' wrongful conduct, the Plaintiffs were damaged by paying in whole or in part for Xarelto and for Plaintiff's medical treatment.

238. As a direct and proximate result of the Defendants' violations of unfair trade practices, the Plaintiffs sustained economic losses and other damages for which the Plaintiffs are entitled to statutory and compensatory damages and attorneys' fees, in an amount to be proven at trial.

**ELEVENTH CAUSE OF ACTION: LOSS OF CONSORTIUM**

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

240. The Plaintiff, Loretta Boudreaux, was and is the spouse of the Plaintiff, Joseph J. Boudreaux, Jr., and as such, lived and cohabited with him for over 50 years.

241. By reason of the foregoing, the Plaintiff's spouse, Loretta Boudreaux, and their community necessarily paid and have become liable to pay for medical aid, treatment, attendance, and for medications.

242. By reason of the foregoing, the Plaintiff's spouse, Loretta Boudreaux, has been caused, presently and in the future, the loss of his companionship, service and society.

243. As a result of the damages sustained by the Plaintiff, Joseph J. Boudreaux, Jr., as set forth above, the Plaintiffs sustained damage to their marital relationship.

**TWELFTH CAUSE OF ACTION: REDHIBITION (La. C.C. 2520, *et seq.*)**

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

245. The Defendants, as manufacturers and sellers of the defective product/Xarelto, are responsible for damages caused by failure of their product to conform to well-defined standards.

246. In particular, the product/Xarelto contains a vice or defect which rendered it useless or its use so inconvenient that a reasonable buyer would not have purchased it.

247. The Defendants manufactured, sold and promoted the product, Xarelto, and placed the product into the stream of commerce. Under Louisiana law, the seller and the

manufacturer warrants the buyer against redhibitory defects or vices in the things sold. La. C.C. Art. 2520.

248. The product, Xarelto, as sold and promoted by the Defendants possessed a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or was unreasonably dangerous as described above, which rendered the product useless or its use so inconvenient that it must be presumed that a buyer would not have bought the product had he known of the defect.

249. Pursuant to La. C.C. Art. 2520, the Plaintiffs are entitled to obtain a rescission of the sale of the subject product/Xarelto.

250. As the manufacturer of the product, under Louisiana law, the Defendants are deemed to know that the product/Xarelto contained a redhibitory defect. La. C.C. Art. 2520, *et seq*. The Defendants are liable as bad faith sellers for selling a defective product with knowledge of a defect and thus are liable to the Plaintiffs for the price of the subject product/Xarelto, with interest from the purchase date, and attorneys' fees.

## PRAYER FOR RELIEF

**WHEREFORE**, the Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages in excess of the jurisdictional amount, including, but not limited to pain and suffering, emotional distress, loss of enjoyment of life, including, but not limited to, all damages sustained as a result of the Plaintiff's severe bleeding event and other non-economic damages in an amount to be determined at trial of this action;

2. Damages for loss of care, comfort and society and companionship in an amount within the jurisdiction of this Court;
3. Loss of earnings and impaired earning capacity according to proof at the time of trial;
4. The full refund of all purchase costs the Plaintiffs paid for Xarelto;
5. All past, present and future medical and hospital bills, out of pocket expenses, and other economic damages including but not limited to all damages sustained as a result of Plaintiff's severe bleed in an amount to be determined at trial after this action;
6. 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 Plaintiffs in an amount sufficient to punish the Defendants and deter future similar conduct;
7. Prejudgment interest and post judgment interest;
8. Awarding the Plaintiffs reasonable attorneys' fees;
9. Awarding the Plaintiffs the costs of these proceedings; and
10. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

The Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Date: December 1, 2014.

Respectfully Submitted,

/s/ Mekel Alvarez
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