UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ASHLIE FLUITT Plaintiff, V. 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, Defendants.	**CASE NO.:** **SECTION:** **JUDGE:** **MAG. JUDGE:** **JURY TRIAL DEMANDED**

This document relates to:
Robinson v. Janssen Research & Development, LLC, et al (2:14cv2904) &
Goodwin v. Janssen Research & Development, LLC, et al (5:15cv0187)

COMPLAINT

Plaintiff, ASHLIE FLUITT, by and through the undersigned counsel, upon information and belief, at all times hereinafter mentioned, alleges 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 exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff, Plaintiff's decedent and the Defendants.

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

3. 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 its 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 on behalf of ASHLIE FLUITT, daughter of Leland Robinson, Jr., who predeceased his mother HATTIE DEVILLE-GOODWIN. As the surviving granddaughter of Hattie Deville-Goodwin, deceased, Ashlie Fluitt, asserts a claim for the wrongful death of her grandmother (hereinafter "Plaintiff"). Plaintiff's grandmother, Hattie Deville-Goodwin, used Xarelto, also known as rivaroxaban, which is a medication used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

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

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

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

8. These representations were made by Defendants 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 Plaintiff's decedent herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff's grandmother, and 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. As a result of the foregoing acts and omissions, Plaintiff's grandmother, Hattie Deville-Goodwin, (hereinafter sometimes referred to as: "Plaintiff's decedent") was caused to suffer serious and dangerous side effects including inter alia uncontrolled internal bleeding, brain hemorrhage and ultimately death. Plaintiff brings this action for the wrongful death of her biological grandmother, Hattie Deville Goodwin. due to her use of Xarelto.

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

12. Consequently, Plaintiff seeks all damages recoverable as a matter of law as a result of the death of her grandmother due to her use of the Xarelto, including diminished enjoyment of life, loss of love and affection, society, companionship, nurture, guidance and support.

PARTY PLAINTIFF

13. Plaintiff, ASHLIE FLUITT, daughter of Leland Robinson, Jr. (deceased), who predeceased his mother, Hattie Deville Goodwin, at all times relevant hereto, is the biological granddaughter of Hattie Deville Goodwin, deceased, a citizen and resident of the State of Louisiana and is domiciled in the Parish of Iberia, State of Louisiana.

14. Upon information and belief, Hattie Deville Goodwin, deceased, was prescribed Xarelto in the State of Louisiana, in or around September 2014, upon direction of her physician for the treatment of a Deep Vein Thrombosis (DVT).

15. Upon information and belief, Plaintiff's decedent began using Xarelto in or around September 2014 up until approximately November 10, 2014.

16. Upon information and belief, and as a direct and proximate result of the use of Defendants' defective product, Xarelto, Hattie Deville Goodwin experienced an intracranial

bleed on or about November 12, 2014, thereby suffering an irreversible and fatal bleed from the use of Xarelto, a perished at Ochsner Hospital in New Orleans, Louisiana on November 14, 2014.

17. As a direct and proximate result of the use of Defendants' Xarelto, Hattie Deville Goodwin suffered serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries, physical pain and extreme mental anguish, prior to her death; as well as, substantial financial expenses for hospitalization, medical care and funeral expenses.

18. As a direct and proximate result of Defendants' conduct, Plaintiff's decedent, Hattie Deville Goodwin, suffered and incurred damages, including medical expenses and other economic and non-economic damages prior to her death.

PARTY DEFENDANTS

19. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

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

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

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

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

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

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

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

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

28. Upon information and belief, Defendant, JANSSEN PHARM, has derived

substantial revenue from goods and products used in the State of Louisiana.

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

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

31. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at State Road 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

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

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

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

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

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

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

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

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

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

Louisiana.

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

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

43. Upon information and belief, and at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

45. 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.

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

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

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

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

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

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

52. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

54. Upon information and belief, Defendant BAYER CORPORATION is the sole

member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

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

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

57. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey.

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

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

60. Upon information and belief, at all relevant times, Defendant BAYER

HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

61. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMA AG.

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

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

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

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

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

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

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

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

70. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

71. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto and rivaroxaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

72. Defendants received FDA approval for Xarelto, also known as rivaroxaban, on or about July 1, 2011 for the prophylaxis of DVT and PE in patients undergoing hip

replacement or knee replacement surgeries (NDA 022406).

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

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

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

76. 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.

77. 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.)

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

79. 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.)

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

81. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference – namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet.

82. However, in its Quarter Watch 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."

83. 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 over dosage section.

84. 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.

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

86. 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.

87. 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.

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

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

90. On June 6, 2013, Defendants received an untitled letter from the FDA's Office

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

91. Prior to Plaintiff's grandmother's prescription of Xarelto, she became aware of the promotional materials described herein.

92. Prior to Plaintiff's decedent's prescription of Xarelto, her prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or after undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

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

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

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

96. 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.

97. 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."

98. 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.

99. 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.

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

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

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

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

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;

(d) failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;

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

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

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

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

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

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

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

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

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

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

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

102. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 101 (a – o).

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

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

105. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's grandmother's prescribing physicians or Plaintiff's decedent 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 Defendants had not adequately

conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

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

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

108. 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.

109. By reason of the foregoing acts and omissions, Plaintiff's decedent was caused to suffer from uncontrolled internal bleeding, brain hemorrhage and death.

110. By reason of the foregoing acts and omissions, Plaintiff has and will suffer injuries, damages and losses due to the wrongful death of her grandmother and Plaintiff's decedent endured severe emotional and mental anguish, loss of accumulations, medical expenses, and other economic and non-economic damages, before and after her death, as a result of the actions and inactions of the Defendants.

FIRST CAUSE OF ACTION
CONSTRUCTION OR COMPOSITION DEFECT UNDER LA. R.S. 9:2800.55
(PRODUCTS LIABILITY)

111. Plaintiff repeats, reiterates and re-alleges 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.

112. At all times material to this action, Defendants were engaged in the business

of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Xarelto.

113. At all times material to this action, Xarelto was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiff's decedent herein without substantial change in the condition in which it was sold.

114. At all times material to this action, Xarelto was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Xarelto contained manufacturing defects which rendered the subject product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of the Defendants.

115. The subject product manufactured and/or supplied by Defendants was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe, has numerous and serious side effects and causes severe and permanent injuries and/or death. The product was unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.

116. As a result of the foregoing acts and omissions, Plaintiff's decedent was caused

to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries which resulted in her death and caused her to sustain financial expenses for hospitalization and medical care, as well as, funeral expenses.

117. As a result of the foregoing acts and omissions, Plaintiff's decedent suffered and died, and incurred both general and special damages, including medical expenses and other economic and non-economic damages.

SECOND CAUSE OF ACTION
DESIGN DEFECT UNDER LA. R.S. 9:2800.56
(PRODUCTS LIABILITY)

118. Plaintiff repeats, reiterates and re-alleges 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.

119. Xarelto is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

120. At all times material to this action, Xarelto was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiff's decedent herein, without substantial change in the condition in which it was sold.

121. At all times material to this action, Xarelto was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more

of the following particulars:

a. When placed in the stream of commerce, Xarelto contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff's decedent to risks that exceeded the benefits of the subject product, including but not limited to permanent personal injuries and/or death;

b. When placed in the stream of commerce, Xarelto was defective in design and formulation, making the use of Xarelto more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market;

c. Xarelto's design defects existed before it left the control of the Defendants;

d. Xarelto was insufficiently tested;

e. Xarelto caused harmful side effects that outweighed any potential utility; and

f. Xarelto was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff's decedent herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

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

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

124. 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.

125. At the time of Hattie Deville Goodwin's use of Defendants' defective product, Xarelto was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT

for patients undergoing hip and knee replacement surgery.

126. Defendants, with this knowledge, voluntarily designed Xarelto in a dangerous condition for use by the public, and in particular the Plaintiff's decedent.

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

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

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

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

131. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's decedent's injuries and death without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's grandmother's injuries and death without substantially impairing the product's utility.

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

133. Said defects in Defendants' drug Xarelto were a substantial factor in causing Hattie Deville Goodwin's injuries and death.

134. As a result of the foregoing acts and omissions, Plaintiff's grandmother was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries and death, as well as, physical pain and mental anguish, and financial expenses for hospitalization, medical care and funeral expenses.

135. As a result of the foregoing acts and omissions, Plaintiff's decedent suffered and and died and incurred damages, including medical expenses and other economic and non-economic damages.

THIRD CAUSE OF ACTION
INADEQUATE WARNING UNDER LA. R.S. 9:2800.57
(PRODUCTS LIABILITY)

136. Plaintiff repeats, reiterates and re-alleges 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.

137. Xarelto was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff's decedent herein, and her health care providers, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause permanent physical injuries and fatal side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and fatal side effects. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as provided pursuant to La. R.S. 9:2800.57.

138. The subject product manufactured and supplied by Defendants was defective

due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury.

139. Plaintiff's decedent was prescribed and used the subject product for its intended purpose.

140. Plaintiff's decedent could not have discovered any defect in the subject product through the exercise of reasonable care.

141. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

142. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

143. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of permanent physical injuries and fatal side effects.

144. Plaintiff's decedent, individually and through her prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

145. The Defendants had a continuing duty to warn Plaintiff, Plaintiff's decedent and her treating physicians of the dangers associated with the subject product.

146. Had Plaintiff's decedent and/or her treating physicians received adequate warnings regarding the risks of the subject product, she would not have used it.

147. As a result of the foregoing acts and omissions, Plaintiff's decedent was caused to suffer serious and dangerous side effects including but not limited to, life-threatening

bleeding, as well as other severe and personal injuries which resulted in her death and caused her to sustain financial expenses for hospitalization and medical care, as well as, funeral expenses.

148. As a result of the foregoing acts and omissions, Hattie Deville Goodwin, deceased, suffered and died and incurred damages, including medical expenses and other economic and non-economic damages.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY UNDER LA. R.S. 9:2800.58
(PRODUCTS LIABILITY)

149. Plaintiff repeats, reiterates and re-alleges 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.

150. 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.

151. Defendants expressly represented to Plaintiff's decedent, other consumers, and the medical community that Xarelto was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

152. Xarelto does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects and causes severe and permanent injuries and

death.

153. At the time of the making of the express warranties, Defendants knew or should have known of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of the defendants as provided by La. R.S. 9:2800.58.

154. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries and/or death to the user.

155. At all relevant times Xarelto did not perform as safely as an ordinary consumer and the medical community would expect, when used as intended or in a reasonably foreseeable manner.

156. Plaintiff's decedent, other consumers, and the medical community relied upon Defendants' express warranties.

157. 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.

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

159. Defendants expressly represented to Plaintiff's decedent, and her physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk

of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

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

161. As a result of the foregoing acts and omissions, Plaintiff's decedent was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries which resulted in her death and caused her to sustain financial expenses for hospitalization and medical care, as well as, funeral expenses.

162. As a result of the foregoing breaches, Plaintiff's decedent suffered and incurred damages, including medical expenses and other economic and non-economic damages.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

163. Plaintiff repeats, reiterates and re-alleges 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.

164. 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.

165. At all relevant times, 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.

166. Defendants were aware that consumers, including Plaintiff's grandmother, would use Xarelto in the manner intended.

167. Plaintiff's decedent and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell Xarelto only if it was indeed of merchantable quality and safe and fit for its intended use.

168. Defendants breached the implied warranty to consumers, including Plaintiff's grandmother, as Xarelto was not of merchantable quality or safe and fit for its intended use.

169. Consumers, including Plaintiff's decedent and the medical community, reasonably relied upon Defendants' implied warranty for Xarelto.

170. Xarelto reached consumers, including Plaintiff's decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

171. 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.

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

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

174. The Defendants herein breached the aforesaid implied warranties, as their

drug Xarelto was not fit for its intended purposes and uses.

175. As a result of the foregoing acts and omissions, Plaintiff's decedent was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries which resulted in her death and caused her to sustain financial expenses for hospitalization and medical care, as well as, funeral expenses..

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

SIXTH CAUSE OF ACTION
REDHIBITION

177. Plaintiff repeats, reiterates and re-alleges 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.

178. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

179. Defendants sold and promoted Xarelto, which Defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product, sold and promoted by Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff's grandmother is entitled to obtain a rescission of the sale of the subject product.

180. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff's grandmother is entitled to a reduction of the purchase price.

181. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff's decedent for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Defendants are deemed to know that Xarelto possessed a redhibitory defect. La. C.C. art. 2545.

182. As a result of the foregoing acts and omissions, Plaintiff's decedent was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries which resulted in her death and caused her to sustain financial expenses for hospitalization and medical care, as well as, funeral expenses.

183. As a result of the product's redhibitory defects, Plaintiff's decedent suffered and incurred damages, including medical expenses and other economic and non-economic damages.

184. By reason of the foregoing, Plaintiff's decedent suffered injuries and damages as alleged herein and has incurred attorneys' fees which he is entitled to recover from Defendants.

SEVENTH CAUSE OF ACTION
BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

185. Plaintiff repeats, reiterates and re-alleges 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.

186. In addition to warranting against redhibitory defects, Defendants warranted that the subject product is reasonably fit for its ordinary and intended use. La. C.C. art. 2524.

187. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries and death. As a result, Defendants' drug is unfit and inherently dangerous for ordinary use.

188. As a direct and proximate result of Defendants' actions, Plaintiff's decedent sustained serious, significant and permanent injuries which resulted in her death. In addition, Plaintiff's grandmother was required to incur substantial medical and hospital expense, as well as, funeral expenses.

189. Plaintiff's grandmother's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, supplies, ambulance and AirMed transfer expenses.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, ASHLIE FLUITT, individually and as the surviving granddaughter of her biological grandmother, Hattie Deville Goodwin, deceased, demands judgment against the Defendants on each of the above-referenced claims and Causes of Action, as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to her loss of love and affection, society,

companionship, nurture, guidance and support from her grandmother;

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

3. Pre-judgment interest;

4. Post-judgment interest;

5. Awarding Plaintiff reasonable attorneys' fees;

6. Awarding Plaintiff the costs of these proceedings; and

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

DEMAND FOR JURY TRIAL

Plaintiff, ASHLIE FLUITT, is entitled to and hereby demands trial by jury as to all issues.

Respectfully submitted,

DOMENGEAUX, WRIGHT ROY
EDWARDS & COLOMB, LLC

November 12, 2015

Elwood C. Stevens, Jr.
_____

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Attorneys for the Plaintiff, Ashlie Fluitt, individually and as surviving granddaughter of Hattie Deville Goodwin, deceased

JS 44 (Rev. 3/13)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

ASHLIE FLUITT

(b) County of Residence of First Listed Plaintiff St. Landry Parish, LA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Elwood C. Stevens, Jr., Domengeaux Wright Roy & Edwards, 556 Jefferson Street, Suite 500, Lafayette, LA 70501, PH: (337) 233-3033

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,

County of Residence of First Listed Defendant New Brunswick, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☑ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☑ 1	1	Incorporated *or* Principal Place of Business In This State	4	4
Citizen of Another State	2	2	Incorporated *and* Principal Place of Business In Another State	5	☑ 5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ■ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities Employment
- ☐ 446 Amer. w/Disabilities Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 U.S.C. 1332; Product liability - defective pharmaceutical, personal injury

VII. Previous Bankruptcy Matters

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☑ Yes ☐ No

IX. RELATED CASE(S) IF ANY

(See instructions): JUDGE Honorable Eldon E. Fallon DOCKET NUMBER MDL NO. 2592

X. This case (check one box) ☑ **Is not a refiling of a previously dismissed action** ☐ is a refiling of case number _____ previously dismissed by Judge _____

DATE 11/12/2015

SIGNATURE OF ATTORNEY OF RECORD /s/ Elwood C. Stevens, Jr.