**UNITED STATES DISTRICT COURT**

**EASTERN DISTRICT OF LOUISIANA**

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| **JOANN VARNADO AND CHRISTIAN VARNADO, individually and on behalf of decedent GERALD VARNADO** | * | **CIVIL ACTION NO.** |
| **Plaintiffs** | * | **JUDGE** |
| **VERSUS** | * | |
| **JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN PHARMACEUTICALS INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER CORPORATION, BAYER HEALTHCARE LLC** | * | **MAGISTRATE JUDGE** |
| **Defendants** | | |

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## COMPLAINT FOR DAMAGES

Plaintiffs, **JOANN VARNADO** and **CHRISTIAN VARNADO**, individually and on behalf of decedent, **GERALD VARNADO**, by and through undersigned counsel, bring this action against Defendants, **JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN PHARMACEUTICALS INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INCBAYER CORPORATION, BAYER HEALTHCARE LLC**, and respectfully 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 Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

## NATURE OF THE CASE

2. This action is brought on behalf of Plaintiffs, **JOANN VARNADO** and **CHRISTIAN VARNADO**, individually and on behalf of Plaintiff-decedent, **GERALD VARNADO**, who used Xarelto also known as rivaroxaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

3. Defendants, **JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, , JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHOMCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER CORPORATION, BAYER HEALTHCARE LLC,** (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

4. 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-decedent and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

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

6. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff-decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Xarelto for use 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 all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff-decedent herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

8. As a result of the foregoing acts and omissions. the Plaintiff-decedent was caused to suffer serious and dangerous side effects including inter alia gastrointestinal hemorrhaging and internal bleeding, which caused his death on July 27, 2014.

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

10. Plaintiffs seek compensatory damages as a result of Plaintiff-decedent's use of the Xarelto, which caused Plaintiff-decedent's death due to gastrointestinal hemorrhaging and internal bleeding.

## PARTY PLAINTIFFS

11. Plaintiff-decedent, **GERALD VARNADO**, born on July 2, 1941, was a person of the full age of majority and resident of the State of Louisiana.

12. Plaintiff, **JOANN VARNADO**, the surviving spouse of Plaintiff-decedent, is a person of the full age of majority and resident of the State of Louisiana.

13. Plaintiff, **CHRISTIAN VARNADO**, the surviving son of Plaintiff-decedent, is a person of the full age of majority and resident of the State of Louisiana.

14. Plaintiff-decedent, **GERALD VARNADO**, first began using Xarelto in or about February 2013, and used Xarelto up through approximately July 25, 2014.

15. As result of using Defendants' Xarelto, Plaintiff-decedent, **GERALD VARNADO**, suffered life-threatening bleeding on or about July 26, 2014, and Plaintiffs suffered severe and permanent injuries, pain and suffering, and emotional distress.

16. The injuries and damages sustained by Plaintiff-decedent and Plaintiffs, **JOANN VARNADO** and **CHRISTIAN VARNADO**, were caused by Defendants' Xarelto.

## PARTY DEFENDANTS

17. 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.

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

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

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

21. 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.

22. 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.

23. 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.

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

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

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

27. 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.

28. 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.

29. 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 Tennessee, with its principal place of business in the State of New Jersey.

30. 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.

31. 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.

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

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

34. 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.

35. 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.

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

37. 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 HEALTH CARE PHARMACEUTICALS, INC.**

38. 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.

39. 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.

40. 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 Tennessee, with its principal place of business located in the State of New York.

41. 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 HEALTH CARE LLC** and as such for purposes of establishing diversity of citizenship, Defendant **BAYER HEALTHCARE LLC** is a citizen of Indiana and Pennsylvania.

42. 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.

43. 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.

## FACTUAL BACKGROUND

44. 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.

45. 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).

46. 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).

47. 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.

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

49. 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.

50. 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.)

51. 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.)

52. 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;

53. 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.

54. 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.

55. 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."

56. 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.

57. 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.

58. 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.

59. 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 of2013.

60. 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.

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

62. 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.

63. 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.

64. Prior to Plaintiff-decedent's prescription of Xarelto, Plaintiffs 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 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.

65. 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.

66. 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, and life-threatening.

67. 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.

68. 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.

69. 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."

70. 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.

71. 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.

72. 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 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;

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

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

n. 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.

73. 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 72 (a -n).

74. 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.

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

76. 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-decedent's prescribing physicians or 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 Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

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

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

79. 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.

80. By reason of the foregoing acts and omissions, Plaintiffs seek compensatory damages as a result of the Plaintiff-decedent's use of Xarelto, which caused the Plaintiff-decedent to suffer from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

81. By reason of the foregoing, Plaintiffs have been severely and permanently injured, including Plaintiff-decedent's premature death.

**FIRST CAUSE OF ACTIONAS AGAINST THE DEFENDANTS (LOUISIANA PRODUCTS LIABILITY ACT)**

82. 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.

83. 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.

84. 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 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 are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as

well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

85. The violations of law by 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 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 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 observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto;

(g) Failing 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, 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 its 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 Plaintiff in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations; and

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

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

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

88. Defendants violated Louisiana law in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that they:

(a) Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with 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) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Xarelto;

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

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

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

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

(g) Failed to warn Plaintiff, 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; and

(h) Were otherwise careless and/or negligent.

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

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

91. Defendants' violations of law were the proximate cause of Plaintiff-decedent's injuries, harm and economic loss which Plaintiff-decedent suffered and/or will continue to suffer.

92. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

**(STRICT PRODUCTS LIABILITY)**

93. 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.

94. 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-decedent.

95. 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.

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

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

98. 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.

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

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

101. At the time of the Plaintiff-decedent's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

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

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

105. 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.

106. 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.

107. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff-decedent in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff-decedent.

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

109. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which arc permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

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

112. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health

consequences from 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.

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

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

115. That said defects in Defendants' drug Xarelto were a substantial factor in causing Plaintiff-decedent's injuries and Plaintiffs' injuries.

116. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

117. 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.

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

119. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff-decedent suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

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

121. 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.

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

123. Defendants expressly represented to Plaintiff-decedent, his 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.

124. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in

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

125. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

126. Plaintiff 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 all if more fully set forth herein.

127. 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.

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

129. 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.

130. 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.

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

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

133. 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.

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

135. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

**(FRAUDULENT MISREPRESENTATION)**

136. 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.

137. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff-decedent, and/or the FDA, and the public in general, that said product, 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.

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

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

140. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff-decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, 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-decedent herein.

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

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

143. 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.

144. 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.

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

146. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

147. 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.

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

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

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

(a) that Xarelto was not as safe as other fonns 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 propbylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) that the risks of adverse events with Xareho were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibri llation, reducing the risk of recurrence of DVT andlor 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 Defendants;

(d) that Defendants were aware ofdangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment *fOT* reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT andlor 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 notlirruted to Iifc-tlueatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other fOnDS 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;

(f) that patients needed 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.

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

152. 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 Plaintiff-decedent in particular.

153 . Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Xarelto was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff-decedent, and 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.

154. Defendants knew that Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Xarelto, as set forth herein.

155. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

**SEVENTH CAUSE OF ACTION AS AGAINST TIJE DEFENDANTS**

**(NEGLIGENT MISREPRESENTATION)**

156. 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.

157. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, 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.

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

159. 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 Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects.

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

162. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

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

**(FRAUD AND DECEIT)**

163. 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.

164. Defendants conducted research and used Xarelto as part of their research.

165. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff-decedent, Plaintiff-decedent's doctors, hospitals, healthcare professionals, and/or the FDA that 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.

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

167. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff-decedent, as well as Plaintiff-decedent's respective healthcare providers and/or the FDA.

168. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

169. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

170. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and/or dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

172. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included false representations that Xarelto was as potentially injurious to the health and/or safety of its intended 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.

173. These representations were all false and misleading.

174. Upon information and belief, 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, 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, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

175. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff-decedent, regarding the safety of Xarelto,

specifically but not limited to Xarelto not having dangerous and serious health and/or safety concerns.

176. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff-decedent, regarding the safety of Xarelto, specifically 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.

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

178. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent, that 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, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

179.. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent, that 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, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and/or 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.

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

181. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff-decedent, that 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, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

183. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff-decedent, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff-decedent, and/or

her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff-decedent, to purchase, use, rely on, request, dispense, recommend, and/or prescribe Xarelto.

184. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, the Plaintiff-decedent, in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment 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.

185. That 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.

186. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff-decedent, as well as his respective healthcare professionals, into a sense of security so that Plaintiff-decedent would rely on the representations and purchase, use and rely on Xarelto and/or that Plaintiff-decedent's respective healthcare providers would dispense, prescribe, and/or recommend the same.

187. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff-decedent, as well as Plaintiff-decedent's respective healthcare professionals would rely upon the information being disseminated.

188.. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Xarelto.

189. That the Plaintiff-decedent, and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

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

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

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

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

194. As a result of the foregoing acts and omissions, the Plaintiff-decedent suffered from life-threatening bleeding and sudden death, and Plaintiffs suffered severe and personal injuries which

are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

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

195. 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.

196. As a result of the foregoing, on July 27, 2014, Plaintiff-decedent, **GERALD VARNADO**, died from complications proximately related to the Defendant's Xarelto.

197. Plaintiff-decedent, **GERALD VARNADO**, left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedent's death have suffered a pecuniary loss including, but not limited to support, income, services and guidance of the Plaintiff-decedent, **GERALD VARNADO**, and were all permanently damaged thereby.

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

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

## PRAYER FOR RELIEF

**WHEREFORE**, 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, including but not limited to Plaintiff-decedent's pain and suffering and Plaintiffs' pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, economic loss, together with interest and costs as provided by law; ;

2. Awarding Plaintiffs reasonable attorneys' fees;

3. Awarding Plaintiffs the costs of these proceedings; and

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

Respectfully submitted:

***/s/ Lawrence J. Centola, III***
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JS 44 (Rev. 12/12)

# 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**
JOANN VARNADO and CHRISTIAN VARNADO, individually and on behalf of decedent, GERALD VARNADO

(b) County of Residence of First Listed Plaintiff _____
*(EXCEPT IN U.S. PLAINTIFF CASES)*

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Lawrence J. Centola, III - Martzell & Bickford
338 Lafayette Street, NOLA 70130
(504) 581-9065

**DEFENDANTS**
JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL ET AL

County of Residence of First Listed Defendant _____
*(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
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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 | TORTS | | FORFEITURE/PENALTY | BANKRUPTCY | OTHER STATUTES |
|---|---|---|---|---|---|
| ☐ 110 Insurance | PERSONAL INJURY | PERSONAL INJURY | ☐ 625 Drug Related Seizure of Property 21 USC 881 | ☐ 422 Appeal 28 USC 158 | ☐ 375 False Claims Act |
| ☐ 120 Marine | ☐ 310 Airplane | ☐ 365 Personal Injury - Product Liability | ☐ 690 Other | ☐ 423 Withdrawal 28 USC 157 | ☐ 400 State Reapportionment |
| ☐ 130 Miller Act | ☐ 315 Airplane Product Liability | ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability | | PROPERTY RIGHTS | ☐ 410 Antitrust |
| ☐ 140 Negotiable Instrument | ☐ 320 Assault, Libel & Slander | ☐ 368 Asbestos Personal Injury Product Liability | | ☐ 820 Copyrights | ☐ 430 Banks and Banking |
| ☐ 150 Recovery of Overpayment & Enforcement of Judgment | ☐ 330 Federal Employers' Liability | PERSONAL PROPERTY | LABOR | ☐ 830 Patent | ☐ 450 Commerce |
| ☐ 151 Medicare Act | ☐ 340 Marine | ☐ 370 Other Fraud | ☐ 710 Fair Labor Standards Act | ☐ 840 Trademark | ☐ 460 Deportation |
| ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) | ☐ 345 Marine Product Liability | ☐ 371 Truth in Lending | ☐ 720 Labor/Management Relations | SOCIAL SECURITY | ☐ 470 Racketeer Influenced and Corrupt Organizations |
| ☐ 153 Recovery of Overpayment of Veteran's Benefits | ☐ 350 Motor Vehicle | ☐ 380 Other Personal Property Damage | ☐ 740 Railway Labor Act | ☐ 861 HIA (1395ff) | ☐ 480 Consumer Credit |
| ☐ 160 Stockholders' Suits | ☐ 355 Motor Vehicle Product Liability | ☐ 385 Property Damage Product Liability | ☐ 751 Family and Medical Leave Act | ☐ 862 Black Lung (923) | ☐ 490 Cable/Sat TV |
| ☐ 190 Other Contract | ☐ 360 Other Personal Injury | | ☐ 790 Other Labor Litigation | ☐ 863 DIWC/DIWW (405(g)) | ☐ 850 Securities/Commodities/ Exchange |
| ☐ 195 Contract Product Liability | ☐ 362 Personal Injury - Medical Malpractice | | ☐ 791 Employee Retirement Income Security Act | ☐ 864 SSID Title XVI | ☐ 890 Other Statutory Actions |
| ☐ 196 Franchise | | | | ☐ 865 RSI (405(g)) | ☐ 891 Agricultural Acts |
| | | | | | ☐ 893 Environmental Matters |
| | | | | | ☐ 895 Freedom of Information Act |
| | | | | | ☐ 896 Arbitration |
| | | | | FEDERAL TAX SUITS | ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision |
| | | | | ☐ 870 Taxes (U.S. Plaintiff or Defendant) | ☐ 950 Constitutionality of State Statutes |
| | | | | ☐ 871 IRS—Third Party 26 USC 7609 | |

| REAL PROPERTY | CIVIL RIGHTS | PRISONER PETITIONS | IMMIGRATION |
|---|---|---|---|
| ☐ 210 Land Condemnation | ☐ 440 Other Civil Rights | Habeas Corpus: | ☐ 462 Naturalization Application |
| ☐ 220 Foreclosure | ☐ 441 Voting | ☐ 463 Alien Detainee | ☐ 465 Other Immigration Actions |
| ☐ 230 Rent Lease & Ejectment | ☐ 442 Employment | ☐ 510 Motions to Vacate Sentence | |
| ☐ 240 Torts to Land | ☐ 443 Housing/ Accommodations | ☐ 530 General | |
| ☐ 245 Tort Product Liability | ☐ 445 Amer. w/Disabilities - Employment | ☐ 535 Death Penalty | |
| ☐ 290 All Other Real Property | ☐ 446 Amer. w/Disabilities - Other | Other: | |
| | ☐ 448 Education | ☐ 540 Mandamus & Other | |
| | | ☐ 550 Civil Rights | |
| | | ☐ 555 Prison Condition | |
| | | ☐ 560 Civil Detainee - Conditions of Confinement | |

**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**
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*: 28 USC 1332
Brief description of cause: Xarelto - Products Liability - Wrongful Death

**VII. 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

**VIII. RELATED CASE(S) IF ANY** *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

DATE 9-25-14 SIGNATURE OF ATTORNEY OF RECORD

**FOR OFFICE USE ONLY**

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOANN VARNADO and CHRISTIAN VARNADO, INDIVIDUALLY AND ON BEHALF OF DECEDENT, GERALD VARNADO

*Plaintiff(s)*

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC ET AL

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research & Development LLC
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SERVED VIA CERTIFIED MAIL

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOANN VARNADO and CHRISTIAN VARNADO, INDIVIDUALLY AND ON BEHALF OF DECEDENT, GERALD VARNADO

*Plaintiff(s)*

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC ET AL

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharm
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SERVED VIA CERTIFIED MAIL

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOANN VARNADO and CHRISTIAN VARNADO, INDIVIDUALLY AND ON BEHALF OF DECEDENT, GERALD VARNADO

*Plaintiff(s)*

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC ET AL

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Health Care Pharmaceuticals Inc.
67 Whippany Road
Whippany, NJ 07981

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

☑ Other *(specify)*: SERVED VIA CERTIFIED MAIL

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOANN VARNADO and CHRISTIAN VARNADO, INDIVIDUALLY AND ON BEHALF OF DECEDENT, GERALD VARNADO

*Plaintiff(s)*

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC ET AL

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Healthcare LLC
6 W. Belt
Wayne, NJ 07470-6806

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SERVED VIA CERTIFIED MAIL

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOANN VARNADO and CHRISTIAN VARNADO, INDIVIDUALLY AND ON BEHALF OF DECEDENT, GERALD VARNADO

*Plaintiff(s)*

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC ET AL

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Corporation
100 Bayer Road
Pittsburgh, Pennsylvania 15205

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SERVED VIA CERTIFIED MAIL

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc: