

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

IN RE: XARELTO (RIVAROXABAN)  
PRODUCTS LIABILITY LITIGATION

**MDL No. 2592**

JOSEPH GREFER, individually, and on behalf of  
his deceased spouse, PATSY RUTH MOLE  
GREFER,

**SECTION: L  
JUDGE FALLON  
MAG. JUDGE NORTH**

Plaintiff,

**COMPLAINT AND JURY DEMAND**

JANSSEN RESEARCH & DEVELOPMENT  
LLC f/k/a JOHNSON AND JOHNSON  
PHARMACEUTICAL RESEARCH AND  
DEVELOPMENT LLC, JANSSEN ORTHO LLC,  
JANSSEN PHARMACEUTICALS, INC.  
f/k/a JANSSEN PHARMACEUTICA INC.  
f/k/a ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC.,  
JOHNSON & JOHNSON COMPANY,  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.,  
BAYER PHARMA AG,  
BAYER CORPORATION,  
BAYER HEALTHCARE LLC,  
BAYER HEALTHCARE AG, and BAYER AG,

**Civil Action No.:** \_\_\_\_\_

Defendants.

**COMPLAINT**

1. Plaintiff, Joseph Grefer, individually, and on behalf of his deceased spouse, Patsy Ruth Mole Grefer, by and through the undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

**PARTY PLAINTIFF**

2. Decedent, Patsy Ruth Mole Grefer, ingested Xarelto from approximately August 2015 to January 2016. On or about January 6, 2015, Decedent suffered an intracranial

hemorrhage, which required surgery and an extended hospitalization, as a direct and proximate result of the unreasonably dangerous characteristics of the prescription drug Xarelto manufactured and sold by Defendants. Decedent Patsy Ruth Mole Grefer passed away on June 13, 2016. Decedent was a resident of Jefferson Parish in the state of Louisiana. Decedent was married at the time of her death and is represented herein by her spouse, Joseph Grefer, acting herein as representative of her estate.

3. Plaintiff Joseph Grefer is a citizen and resident of Jefferson Parish in the state of Louisiana.

4. Decedent was unaware that the unreasonably dangerous characteristics of Xarelto caused her internal bleeding.

5. As a direct and proximate result of Defendants' conduct, Decedent experienced physical pain, mental anguish, medical expenses, loss of enjoyment of life, and other economic and non-economic damages. Plaintiff experienced a loss of consortium, incurred medical, funeral and burial expenses, and incurred other economic and non-economic damages.

#### **PARTY DEFENDANTS**

6. 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 in New Jersey. Defendant JANSSEN R&D's sole member is Janssen Pharmaceuticals, Inc., which is a Pennsylvania corporation with a principal place of business in New Jersey. Accordingly, JANSSEN R&D is a citizen of Pennsylvania and New Jersey for purposes of determining diversity under 28 U.S.C. § 1332.

7. As part of its business, JANSSEN R&D is involved in the research, development,

sales, and marketing of pharmaceutical products including Xarelto.

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

9. 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 Xarelto are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat Deep Vein Thrombosis (“DVT”) and Pulmonary Embolism (“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.

10. 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 in New Jersey.

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

12. 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.

13. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter

referred to as “JANSSEN ORTHO”) is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated in Ireland with a principal place of business in Puerto Rico. Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland and Puerto Rico for purposes of determining diversity under 28 U.S.C. § 1332.

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

15. 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.

16. Defendant Johnson & Johnson (hereinafter referred to as “J&J”) is a fictitious name adopted by Defendant Johnson & Johnson Company, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

17. As part of its business, J&J, and its “family of companies,” is involved in the research, development, sales, and marketing of pharmaceutical products, including Xarelto.

18. 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.

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

20. 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.

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

22. 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 was formerly known as Schering AG and is the same corporate entity as Schering AG.

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

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

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

26. 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.

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

28. Upon information and belief, BAYER HEALTHCARE PHARMACEUTICALS, INC. is owned by Defendant BAYER CORPORATION.

29. At all 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.

30. 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 at 100 Bayer Blvd, Whippany, New Jersey 07981-1544.

- (a) Upon information and belief, from on or about the early January 1, 2003 until on or about late December, 2014, BAYER HEALTHCARE LLC's sole member was Bayer Corporation, and is wholly owned by Bayer Corporation, which is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

(b) Upon information and belief, from on or about early January, 2015 to on or about June 30, 2015, BAYER HEALTHCARE LLC's sole member was Bayer Medical Care, Inc., and is wholly owned by Bayer Medical Care, Inc., which is a Delaware Corporation, with its principal place of business at 1 Medrad Dr., Indianola, Pennsylvania 15051.

(c) Upon information and belief, from on or about July 1, 2015 to the present, BAYER HEALTHCARE LLC's members are:

- Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;
- NippoNex Inc., a Delaware corporation with its principal place of business in New York;
- Bayer West Coast Corporation, a Delaware Corporation with its principal place of business in California;
- Bayer Essure Inc., a Delaware corporation with its principal place of business in California;
- Bayer Consumer Care Holdings, LLC, a limited liability company formed in Delaware with its principal place of business in New Jersey;
- Dr. Scholl's LLC, a limited liability company, formed in Delaware with its principal place of business in California;
- Coppertone LLC, a limited liability company, formed in Delaware with its principal place of business in California;

- MiraLAX LLC, a limited liability company, formed in Delaware with its principal place of business in California; and,
- Bayer HealthCare U.S Funding LLC, a limited liability company a limited liability company, formed in Delaware with its principal place of business in Pennsylvania.

31. Accordingly, BAYER HEALTHCARE LLC is a citizen of Delaware, New Jersey, New York, Indiana, Pennsylvania, and California for purposes of determining diversity under 28 U.S.C. § 1332.

32. 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.

33. 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.

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



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

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

37. 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.

38. Defendants Janssen Research & Development LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Johnson & Johnson, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare AG, and Bayer AG, shall be referred to herein individually by name or jointly as “Defendants.”

39. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

40. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

41. At all times relevant, Defendants were engaged in the business of developing,

designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the drug Xarelto.

### **JURISDICTION AND VENUE**

42. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332, in that in each of the constituent actions there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

43. Defendants have significant contacts in the vicinage of Plaintiff's and Decedent's residence such that they are subject to the personal jurisdiction of the court in that vicinage.

44. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the vicinage of Decedent's residence, as well as in this district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in both districts.

45. Pursuant to the Transfer Order of the Judicial Panel on Multidistrict Litigation, *In re Xarelto (Rivaroxaban) Products Liab. Litig.*, 2014 WL 7004048 (J.P.M.L. June 12, 2014), venue is also proper in this jurisdiction pursuant to 28 U.S.C. § 1407.

### **FACTUAL ALLEGATIONS**

#### **A. Nature of the Case**

46. Plaintiff brings this case against Defendants for damages associated with Decedent's ingestion of the pharmaceutical drug Xarelto, which was designed, manufactured, marketed, sold and distributed by Defendants. Specifically, Decedent suffered serious physical pain and suffering, death, medical, hospital and surgical expenses, and Plaintiff suffered various losses, including a loss of consortium as a direct result of Decedent's use of Xarelto.

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

48. Xarelto was introduced in the United States (“U.S.”) on July 1, 2011, and is part of a class of drugs called New Oral Anticoagulants (“NOACs”).

49. This class of NOACs, which also includes Pradaxa and Eliquis, is marketed as the next generation of blood-thinning drugs to replace warfarin (Coumadin); an established safe treatment for preventing stroke and systemic embolism for the past 60 years.

50. 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.

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

52. 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 Xarelto was superior (based on the Defendants’ definition) to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty, accompanied by similar rates of bleeding. However, the studies also showed a greater bleeding incidence with Xarelto 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, randomized 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.).

53. Despite these findings, the RECORD studies were flawed in design and conducted in a negligent manner. In fact, FDA Official Action Indicated (“OAI”)—rated inspections in 2009 disclosed rampant violations including, “systemic discarding of medical records,” unauthorized unblinding, falsification, and “concerns regarding improprieties in randomization.” As a result, the FDA found that the RECORD 4 studies were so flawed that they were deemed unreliable. (Seife, Charles, *Research Misconduct Identified by US Food and Drug Administration*, *JAMA Intern. Med* (Feb. 9, 2015)).

54. Nevertheless, Defendants 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). 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”).

55. The Rocket AF study showed that Xarelto was non-inferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, “bleeding from gastrointestinal sites, including upper,

lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion.” (Patel, M.R., et al. Rivaroxaban versus warfarin in Nonvalvular Atrial Fibrillation. *N. Engl. J. Med.* 2011; 365:883-91.)

56. The ROCKET AF study compared warfarin to Xarelto. Thus, for the study to be well designed and meaningful, the warfarin study group would have to be well managed because warfarin’s safety and efficacy is dose dependent. In other words, if the warfarin group was poorly managed, it would be easy for Xarelto to appear non-inferior to warfarin, which, in turn, would provide Defendants a study to “support” Xarelto’s use.

57. In fact, in the ROCKET AF study, the warfarin group was not well managed. The warfarin group in the ROCKET AF study was the worst managed warfarin study group in any previously reported clinical trial involving warfarin.

58. The poor management of the warfarin group in the ROCKET AF study was not lost on the FDA, which noted “the data comparing [Xarelto] to warfarin are not adequate to determine whether [Xarelto] is as effective for its proposed indication in comparison to warfarin when the latter is used skillfully.” FDA Advisory Committee Briefing document. P. 10.

59. Public Citizen also noticed the poor control in the warfarin group. Public Citizen wrote the FDA, stating they “strongly oppose FDA approval... The 3 ROCKET AF trial conducted in support of the proposed indication had a suboptimal control arm...” <http://www.citizen.org/documents/1974.pdf>.

60. Another problem with the ROCKET AF study was Xarelto’s once-a-day dosing. The FDA clinical reviewers stated that “the sponsor’s rationale for evaluating only once daily dosing during Phase 3 is not strong. Most importantly, there is clinical information from Phase 2

trials ... and from clinical pharmacology studies suggesting that twice daily dosing, which would produce lower peak blood levels and higher trough blood levels of [Xarelto], might have been associated with greater efficacy and/or a better safety profile.” FDA advisory Committee Briefing document p. 100.

61. Dr. Steven E. Nissen, more sharply, stated “my concern was that the dose was selected more for a marketing advantage rather than for the scientific data that was available, and was a mistake...” FDA Advisory Meeting Transcript p. 287.

62. Furthermore, the FDA expressed desirability in monitoring Xarelto dosage within their NDA approval memo based on the ROCKET studies. The clinical pharmacology in these studies demonstrated a linear correlation between rivaroxaban (Xarelto) levels and prothrombin time (“PT”); and subsequently a correlation between PT and the risk of bleeding. At this time, Defendants were aware of the correlation between Xarelto dosage and bleeding risks, but had “not chosen to utilize this information.” (NDA 202439 Summary Review, p. 9). At all relevant times, Defendants’ controlled the contents of their label as demonstrated by their decision to go forward without regard to the FDA’s suggestion to utilize this information.

63. 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.

64. 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 an 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 Xarelto 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.)

65. 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.

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

67. Defendants market and promote Xarelto as a single daily dose pill that does not require the need to measure a patient's blood plasma levels, touting it more convenient than warfarin, and does not limit a patient's diet. The single dose and no blood testing requirements or dietary constraints are marked by Defendants as the "Xarelto Difference."

68. However, Xarelto's clinical studies show that Xarelto is safer and more effective when there is blood monitoring, dose adjustments and twice a day dosing.

69. 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.”

70. The use of Xarelto without appropriate blood monitoring, dose adjustment and twice a day dosing can cause major, life-threatening bleeding events. Physicians using Xarelto have to be able to balance the dose so that the blood is thinned enough to reduce the risk of stroke, but not thinned so much as to increase the risk for a major bleeding event. The Defendants were aware of this risk and the need for blood monitoring but have failed to disclose this vital health information to patients, doctors and the FDA.

71. Importantly, Xarelto’s significant risk of severe, and sometimes fatal, internal bleeding has no antidote to reverse its effects, 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, did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdose section.

72. The FDA’s adverse event data indicates staggering, serious adverse events that have been associated with Xarelto.

73. 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.

74. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE



reports were filed with the FDA, 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.

75. 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.”

76. 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.

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

78. Despite the clear signal generated by the SAE data, Defendants did not tell consumers, health care professionals and the scientific community about the dangers of Xarelto, nor did Defendants perform further investigation into the safety of Xarelto.

79. 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 the need for dose adjustments;
- (e) failed to disclose the need to twice daily dosing;
- (f) failed to warn about the need for blood monitoring;
- (g) failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;
- (h) failed to adequately disclose in the “Warnings” Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;
- (i) failed to advise prescribing physicians, such as the Decedent’s physicians, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;
- (j) failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;
- (k) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;
- (l) 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 stomach;
- (m) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;
- (n) 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;
- (o) 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;
- (p) failed to include a “**BOXED WARNING**” about serious bleeding events associated with Xarelto;
- (q) failed to include a “**BOLDED WARNING**” about serious bleeding events associated with Xarelto; and

- (r) in the “Medication Guide” intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose the need for blood monitoring or 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.

80. 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 Paragraph 74 (a – r).

81. Despite the wealth of scientific evidence, Defendants have ignored the increased risk of the development of the aforementioned injuries associated with the use of Xarelto, but they have, through their marketing and advertising campaigns, urged consumers to use Xarelto without regular blood monitoring or instead of anticoagulants that present a safer alternative.

**B. Over-Promotion of Xarelto**

82. Xarelto is the second most prescribed drug for treatment of atrial fibrillation, behind only Coumadin (warfarin), and achieved blockbuster status with sales of approximately \$2 billion dollars in 2013.

83. Defendants spent significant amounts of 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 fiscal 2013, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

84. Defendants' aggressive and misrepresentative marketing of a "Xarelto Difference" lead to an explosion in Xarelto sales. The "Xarelto Difference," *i.e.*, was once a day dosing without blood monitoring. In fact, the "Xarelto Difference" was nothing more than a marketing campaign based on flawed science.

85. As a result of Defendants' aggressive marketing efforts, in its first full year 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 \$1 billion, which is the threshold commonly referred to as "blockbuster" status in the pharmaceutical industry. In fact, Xarelto sales ultimately reached approximately \$2 billion for the 2013 fiscal year, and 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 ("DTC") advertising campaigns that were designed to influence patients to make inquiries to their prescribing physicians about Xarelto and/or request prescriptions for Xarelto.

89. In the course of these DTC advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systemic embolism, failed to disclose the need for dose adjustments, failed to disclose the need for blood monitoring, and 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 Decedent's ingestion of Xarelto, Decedent became aware of the promotional materials described herein.

92. Prior to Decedent's prescription of Xarelto, Decedent's prescribing physician received promotional materials and information from sales representatives of Defendants claiming 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 requiring blood monitoring, dose adjustments, twice a day dosing or 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 about the need for blood monitoring, dose adjustments, and twice a day dosing, and failed to 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.

95. Prior to applying to the FDA 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.

96. As a result of Defendants' claim regarding the effectiveness and safety of Xarelto, Decedent's medical providers prescribed and Decedent ingested Xarelto.

**C. The Decedent's Use of Xarelto and Resulting Injuries**

97. By reason of the foregoing acts and omissions, Decedent was caused to suffer from life-threatening bleeding, as well as other severe and personal injuries, and wrongful death, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings, among other damages.

98. 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.

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

could cause life-threatening bleeding, presented a risk of life-threatening bleeding 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.

100. 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.

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

102. Upon information and belief, Defendants failed to warn Decedent and her healthcare providers regarding the need for blood monitoring, dose adjustments and failed to warn of the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening, associated with Xarelto.

103. 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.

104. Defendants' fraudulent concealment and misrepresentations were designed to prevent, and did prevent, the public and the medical community at large from discovering the risks and dangers associated with Xarelto and Decedent from discovering, and/or with reasonable diligence being able to discover, their causes of action.

105. Defendants' fraudulent representations and concealment evidence flagrant, willful, and depraved indifference to health, safety, and welfare. Defendants' conduct showed willful misconduct, malice, fraud, wantonness, oppression, and that entire want of care that raises the presumption of conscious indifference to the consequences of said conduct.

106. By reason of the forgoing acts and omissions, Decedent has suffered damages and harm, including, but not limited to, personal injury, death, medical expenses, other economic harm, and Plaintiff suffered damages, including loss of consortium, services, society, companionship, love and comfort.

**CLAIMS FOR RELIEF**

**COUNT I  
(Redhibition)**

107. 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.

108. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520.

109. Defendants sold and promoted Xarelto, and Xarelto 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 she known of the defect. Pursuant to La. C.C. art. 2520, Decedent's survival representative is entitled to obtain a rescission of the sale of the subject product.

110. Xarelto 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, Decedent is entitled to a reduction of the purchase price.

111. 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.

112. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to 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.

113. As a result of the product's redhibitory defects, Decedent was caused to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

114. By reason of the foregoing acts and omissions, Plaintiff, on behalf of Decedent, has incurred damages, including medical expenses and other economic damages, and attorneys' fees.

**COUNT II**  
**(DESIGN DEFECT – La. R.S. 9:2800.56)**

115. 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.

116. 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.

117. 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 Decedent, without substantial change in the condition in which it was sold.

118. 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 Decedent to risks that exceeded the benefits of the subject product, including but not limited to permanent personal injuries;
- 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 Decedent, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Decedent.

119. 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.

120. 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.

121. 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.

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

123. Defendants, with this knowledge, voluntarily designed Xarelto in a dangerous condition for use by the public, and in particular Decedent.

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

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

126. 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.

127. 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.

128. 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 Decedent's injuries 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 Decedent's injuries without substantially impairing the product's utility.

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

130. The defects in Defendants' drug Xarelto were a substantial factor in causing Decedent's injuries.

131. By reason of the foregoing acts and omissions, Decedent's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

132. By reason of the foregoing acts and omissions, Plaintiff, individually and on behalf of Decedent, has suffered and incurred both consortium and survival damages, including medical expenses, loss of consortium, loss of enjoyment of life, and other economic and non-economic damages.

**COUNT III**  
**(INADEQUATE WARNING – La. R.S. 9:2800.57)**

133. 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.

134. Xarelto was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Decedent, 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 side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and 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.

135. 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.

136. Decedent was prescribed and used the subject product for its intended purpose.

137. Decedent could not have discovered any defect in the subject product through the exercise of reasonable care.

138. 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.

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

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

141. Decedent, individually and through her prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

142. The Defendants had a continuing duty to warn Decedent of the dangers associated with the subject product.

143. Had Decedent received adequate warnings regarding the risks of the subject

product, she would not have used it.

144. By reason of the foregoing acts and omissions, Decedent's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

145. By reason of the foregoing acts and omissions, Plaintiff, individually and on behalf of Decedent, has suffered and incurred consortium and survival damages, including medical expenses, loss of consortium, loss of enjoyment of life, and other economic and non-economic damages.

**COUNT IV**  
**(BREACH OF EXPRESS WARRANTY - La. R.S. 9:2800.58)**

146. 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.

147. 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 to act as a prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

148. Defendants expressly represented to 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.

149. 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.

150. 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.

151. 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 to the user.

152. 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.

153. Decedent, other consumers, and the medical community relied upon Defendants' express warranties.

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

155. Defendants breached the aforesaid express warranties, as their drug Xarelto was defective.

156. Defendants expressly represented to Decedent, 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 to act as a 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.

157. 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.

158. By reason of the foregoing acts and omissions, Decedent's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

159. By reason of the foregoing acts and omissions, Plaintiff, individually and on behalf of Decedent, incurred consortium and survival damages, including medical expenses, loss of consortium, loss of enjoyment of life, and other economic and non-economic damages.

**COUNT V**  
**(BREACH OF IMPLIED WARRANTY OF**  
**MERCHANTABILITY AND FITNESS)**

160. 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.

161. 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.



162. 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.

163. Defendants were aware that consumers, including Decedent, would use Xarelto in the manner intended.

164. 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.

165. Defendants breached the implied warranty to consumers, including Decedent, as Xarelto was not of merchantable quality or safe and fit for its intended use.

166. Consumers, including Decedent, and the medical community, reasonably relied upon Defendants' implied warranty for Xarelto.

167. Xarelto reached consumers, including Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.

168. 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.

169. 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.

170. 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.

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

172. By reason of the foregoing acts and omissions, Decedent's use of Xarelto caused her to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

173. By reason of the foregoing acts and omissions, Plaintiff, individually and on behalf of Decedent, has suffered and incurred consortium and survival damages, including medical expenses, loss of consortium, loss of enjoyment of life, and other economic and non-economic damages.

**COUNT VI**  
**(BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE)**

174. 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.

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

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

177. As a direct and proximate cause of Defendants' actions, Decedent was caused to suffer from internal bleeding, as well as physical pain, mental anguish, and ultimately death.

178. By reason of the foregoing acts and omissions, Plaintiff, individually and on behalf of Decedent, have incurred damages, including medical expenses, loss of support/income, and other economic damages.

**COUNT IX**  
**(FRAUD)**

179. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Decedent's and Plaintiff's resident State.

180. Prior to Decedent's use of Xarelto and during the period in which Decedent actually used Xarelto, Defendants fraudulently suppressed material information regarding the safety and efficacy of Xarelto, including information regarding increased adverse events, pre and post marketing deaths, and the high number of severe adverse event reports compared to other anticoagulants and the need for blood monitoring and dose adjustments for the safe and effective use of Xarelto. Furthermore, Defendants fraudulently concealed the safety information about the use of Xarelto. As described above, Xarelto has several well-known serious side-effects that are not seen in other anticoagulants. Decedent believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Xarelto strong.

181. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Decedent, 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.

182. These representations were made by said Defendants with the intent of defrauding and deceiving the Decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and

healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with 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 Decedent herein.

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

184. In reliance upon said representations, Decedent was induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

185. 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.

186. 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.

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

188. Defendants fraudulently concealed the safety issues associated with Xarelto including the need for blood monitoring and dose adjustments in order to induce physicians to prescribe Xarelto and for patients, including Decedent, to purchase and use Xarelto.

189. At the time Defendants concealed the fact that Xarelto was not safe, Defendants were under a duty to communicate this information to Decedent, physicians, the FDA, the

healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Xarelto.

190. Defendants, at all times relevant hereto, withheld information from the FDA which they were required to report.

191. Decedent and the Decedent's prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of Xarelto.

192. Decedent's prescribing physicians were not provided with the necessary information by the Defendants, to provide an adequate warning to the Decedent.

193. Xarelto was improperly marketed to the Decedent and her prescribing physicians as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about Xarelto's risks.

194. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Decedent and Decedent's prescribing physicians, Defendants caused or contributed to Decedent's injuries and death.

195. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Decedent. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Xarelto. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

196. Defendants' fraud also acted to conceal their malfeasance which actions tolled Decedent's and Plaintiff's statute of limitations because only Defendants knew the true dangers

associated with the use of Xarelto as described herein. Defendants did not disclose this information to the Decedent, their prescribing physicians, the healthcare community and the general public. Without full knowledge of the dangers of Xarelto, Decedent could not evaluate whether a person who was injured by Xarelto had a valid claim.

197. Defendants widely advertised and promoted Xarelto as a safe and effective medication and/or as a safe and effective means of reducing 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.

198. Defendants' advertisements regarding Xarelto falsely and misleadingly stated that blood monitoring and dose adjustments were not necessary for safe and effective use of the drug, misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Decedent, to purchase such product. Decedent relied on these material misrepresentations when deciding to purchase and consume Xarelto.

199. Defendants had a duty to disclose material information about serious side-effects to consumers such as Decedent.

200. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Xarelto as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Decedent, to purchase Defendants' dangerous product.

201. Had Decedent been aware of the hazards associated with Xarelto, Decedent would have employed appropriate blood monitoring, consumed a different anticoagulant with a better

safety profile, or not have consumed the product that led proximately to Decedent's injuries and death.

202. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Xarelto, for the purpose of preventing consumers, such as Decedent, from discovering these hazards.

**COUNT X**  
**(VIOLATION OF CONSUMER PROTECTION LAWS/CONSUMER FRAUD LAWS)**

203. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

204. Decedent used Xarelto and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

205. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and,
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

206. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Xarelto.

207. Defendants violated consumer protection laws of various states.

208. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side effects related to the use of Xarelto and of the true state of Xarelto's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Decedent, in the marketing and advertising campaign described herein.

209. Defendants' conduct in connection with Xarelto was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

210. As a result of these violations of consumer protection laws, Decedent has incurred and will incur; serious physical injury, death, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

**COUNT XI**  
**(LOSS OF CONSORTIUM)**

211. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Decedent's and Plaintiff's resident State.

212. At all relevant times hereto, Plaintiff has suffered injuries and losses as a result of the Decedent's injuries from Xarelto.

213. For the reasons set forth herein, Plaintiff has necessarily paid and has become



liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

214. For the reasons set forth herein, Plaintiff has suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

215. Plaintiff has suffered great emotional pain and mental anguish.

216. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and severally for all general, special and equitable relief to which Plaintiff is entitled by law.

**COUNT XII**  
**(SURVIVAL ACTION)**

217. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Decedent's and Plaintiff's resident State.

218. As a direct and proximate result of the conduct of Defendants, where appropriate, Plaintiff Decedent, prior to her death, were obligated to spend various sums of money to treat his or her injuries, which debts have been assumed by the Estate. As a direct and proximate cause of the aforesaid, Decedent was caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of her death; and, as a direct and proximate result of the aforesaid, Decedent suffered a loss of earnings and earning capacity. Plaintiff brings this claim on behalf of

Decedent's estates under applicable state statutory and/or common laws.

219. As a direct and proximate result of the conduct of Defendants, Decedent and Plaintiff, until the time of Decedent's death, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

220. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Plaintiff and Decedent relationships until the date of her death, Plaintiff has and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Decedent's heirs, as Administrators or beneficiaries of the estate of the Decedent, bring the claim on behalf of the estate for damages under applicable statutory and/or common laws, and in their own right.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action awarding all amounts which are reasonable in the premises, including:

- a. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium and other non-economic damages in an amount to be determined at trial of this action;
- b. Economic damages in the form of medical expenses, out of pocket expenses, funeral and burial expenses, and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference

for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

- d. Prejudgment interest;
- e. Postjudgment interest;
- f. Plaintiff's reasonable attorneys' fees when applicable;
- g. Plaintiff's costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury as to all issues.

Dated: December 29, 2016

By:

/s/ M. Palmer Lambert

Gerald E. Meunier (#9471)

M. Palmer Lambert (#33228)

GAINSBURGH, BENJAMIN, DAVID,

MEUNIER & WARSHAUER L.L.C.

2800 Entergy Centre

1100 Poydras Street

New Orleans, LA 70163

Phone: (504) 521-7643

Fax: (504) 528-9973

[gmeunier@gainsben.com](mailto:gmeunier@gainsben.com)

[plambert@gainsben.com](mailto:plambert@gainsben.com)

*Attorneys for Plaintiff*

**SERVICE LIST:**

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

One Johnson & Johnson Plaza

New Brunswick, NJ 08933

**JANSSEN ORTHO LLC**

Through its registered agent:  
The Corporation Trust Company  
Corporation Trust Center  
1209 Orange Street  
Wilmington, DE 19801

**JANSSEN PHARMACEUTICALS, INC.  
f/k/a JANSSEN PHARMACEUTICA INC.  
f/k/a ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC.**

One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

**JOHNSON & JOHNSON COMPANY**

One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

**BAYER HEALTHCARE PHARMACEUTICALS, INC.**

Through its designated representative (via certified mail, return receipt requested):  
SOP Department  
Corporation Service Company  
Suite 400  
2711 Centerville Road  
Wilmington, DE 19808

**BAYER PHARMA AG**

Through its designated representative (via registered mail, return receipt requested):  
Attn: Eva Gardyan-Eisenlohr  
General Counsel  
Muellerstrasse 178  
13353 Berlin  
GERMANY

**BAYER CORPORATION**

Service withheld pursuant to Pretrial Order No. 10

**BAYER HEALTHCARE LLC**

Service withheld pursuant to Pretrial Order No. 10

**BAYER HEALTHCARE AG**

Service withheld pursuant to Pretrial Order No. 10

**BAYER AG**

Service withheld pursuant to Pretrial Order No. 10

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

JOSEPH GREFER, INDIVIDUALLY, AND ON BEHALF OF HIS DECEASED SPOUSE, PATSY RUTH MOLE GREFER

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

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

Gerald E. Meunier and M. Palmer Lambert, Gainsburgh Benjamin David Meunier & Warshauer, LLC, 2800 Energy Centre, 1100 Poydras Street, New Orleans, Louisiana 70163-2800, 504/522-2304

DEFENDANTS

Janssen Research & Development LLC f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC, Janssen Ortho, LLC, Janssen Pharmaceuticals, Inc., et al

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

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

Attorneys (If Known)

James B. Irwin, John Olinde, Susan Sharko and Steven Glickstein

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)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

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

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER 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

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. 1332

Brief description of cause: Xarelto

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 Eldon Fallon DOCKET NUMBER 14-2592

DATE 12/29/2016 SIGNATURE OF ATTORNEY OF RECORD /s/ M. Palmer Lambert

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.  
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.  
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.  
 Original Proceedings. (1) Cases which originate in the United States district courts.  
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.  
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.  
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.  
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.  
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.  
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.  
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

JOSEPH GREFER, INDIVIDUALLY, AND ON
BEHALF OF HIS DECEASED SPOUSE,
PATSY RUTH MOLE GREFER

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 Pharmaceuticals, Inc.
Through its designated representative
SOP Department
Corporation Service Company
Suite 400
2711 Centerville Road
Wilmington, DE 19808

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: Gerald E. Meunier and M. Palmer Lambert
Gainsburgh, Benjamin, David, Meunier & Warshauer, LLC
2800 Energy Center, 1100 Poydras Street
New Orleans, LA 70163-2800
504-522-2304

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)*:

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

JOSEPH GREFER, INDIVIDUALLY, AND ON
BEHALF OF HIS DECEASED SPOUSE,
PATSY RUTH MOLE GREFER

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 Pharma AG
Through its designated representative
Attn: Eva Gardyan-Eisenlohr
General Counsel
Muellerstrasse 178
13353 Berlin
Germany

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: Gerald E. Meunier and M. Palmer Lambert
Gainsburgh, Benjamin, David, Meunier & Warshauer, LLC
2800 Energy Center, 1100 Poydras Street
New Orleans, LA 70163-2800
504-522-2304

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)*:

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: