UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

MARGARET M. GARVY Plaintiff, v. JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG, Defendants.	MDL NO. 2592 SECTION: L JUDGE: ELDON E. FALLON MAG. JUDGE MICHAEL NORTH **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, Margaret Garvy, by and through counsel, files this *Complaint* against Defendants, as follows:

I. PLAINTIFF SPECIFIC ALLEGATIONS

1. Plaintiff, Margaret Garvy (hereinafter "Plaintiff"), ingested Xarelto from approximately May 8, 2014 to May 18, 2014 and suffered hemorrhagic pericardial effusion, pericardial tamponade, and plural effusion on May 18, 2014 as a direct result of Xarelto. Plaintiff Margaret Garvy resides in Maricopa County in the state of Arizona.

II. DEFENDANTS

2. 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.

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

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

5. 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.

6. 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.

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

8. 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.

9. 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.

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

11. 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.

12. 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.

13. 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.

14. 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.

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

16. Upon information and belief, and at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was in the business of an 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.

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

18. 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.

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

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

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

22. 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.

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

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

25. 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.

26. 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:

i. Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;

ii. NippoNex Inc., a Delaware corporation with its principal place of business in New York;

iii. Bayer West Coast Corporation, a Delaware Corporation with its principal place of business in California;

iv. Bayer Essure Inc., a Delaware corporation with its principal place of business in California;

v. Bayer Consumer Care Holdings, LLC, a limited liability company formed in Delaware with its principal place of business in New Jersey;

vi. Dr. Scholl's LLC, a limited liability company, formed in Delaware with its principal place of business in California;

vii. Coppertone LLC, a limited liability company, formed in Delaware with its principal place of business in California;

viii. MiraLAX, LLC, a limited liability company, formed in Delaware with its principal place of business in California; and,

ix. Bayer HealthCare U.S. Funding LLC, a limited liability company, formed in Delaware with its principal place of business in Pennsylvania.

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.

27. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in 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.

28. 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.

29. 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.

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

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

32. 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.

33. 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.”

34. 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.

35. 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.

36. 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.

III. JURISDICTION AND VENUE

37. 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.

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

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

40. 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.

IV. FACTUAL ALLEGATIONS

A. Nature of the Case

41. Plaintiff brings this case against Defendants for damages associated with ingestion of the pharmaceutical drug Xarelto, which was designed, manufactured, marketed, sold and distributed by Defendants. Specifically, Plaintiff suffered various injuries, serious physical pain and suffering, medical, hospital and surgical expenses, loss of consortium, and/or death and funeral expenses as a direct result of her use of Xarelto.

42. 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.

43. 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").

44. 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.

45. 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.

46. 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).

47. 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 trial 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.).

48. 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)).

49. 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").

50. 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.)

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.)

60. 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.

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

62. 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."

63. 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.

64. 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."

65. 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.

66. 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.

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

68. 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.

69. 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 results in death, as compared to only 56 deaths associated with warfarin.

70. 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."

71. 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.

72. Moreover, 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.

73. 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.

74. 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 Plaintiff'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.

75. 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).

76. 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

77. 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.

78. 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.

79. 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.

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

81. 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.

82. 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.

83. 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.

84. 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.

85. 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.

86. Prior to Plaintiff's ingestion of Xarelto, Plaintiff became aware of the promotional materials described herein.

87. Prior to Plaintiff's prescription of Xarelto, Plaintiff'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.

88. 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.

89. 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.

90. 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 of should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

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

C. The Plaintiff's Use of Xarelto and Resulting Injuries

92. By reason of the foregoing acts of omissions, Plaintiff was caused to suffer from life-threatening bleeding, as well as other severe and personal injuries (for some, wrongful death) which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings, among other damages.

93. 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.

94. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's 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.

95. 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.

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

97. Upon information and belief, Defendants failed to warn Plaintiff 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.

98. 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.

99. 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 Plaintiff from discovering, and/or with reasonable diligence being able to discover, her causes of action.

100. 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.

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

V. CLAIMS FOR RELIEF

COUNT I
(STRICT LIABILITY)

102. 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 possible, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

103. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug Xarelto was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

104. 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.

105 Defendants' Xarelto was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

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

107. 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.

108. 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.

109. 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.

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

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

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

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

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

115. 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.

116. 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.

117. 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 in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

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

119. 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 are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

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

121. 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.

122. The Xarelto ingested by Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.

123. Plaintiff did not misuse or materially alter her Xarelto.

124. Defendants are strictly liable for Plaintiff's injuries in the following ways:

a. Xarelto as designed, manufactured, sold and supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell Xarelto;

c. Defendants failed to warn and place adequate warnings and instructions on Xarelto;

d. Defendants failed to adequately test Xarelto;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Xarelto, and,

f. A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

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

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

127. That said defects in Defendants' drug Xarelto were a substantial factor in causing Plaintiff's injuries.

128. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries (in some cases death) which are permanent and lasting in

nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

129. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT II
(MANUFACTURING DEFECT)

130. 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.

131. Xarelto was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants.

132. When it left the control of Defendants, Xarelto was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

133. Xarelto was defective when it left Defendants' control and was placed in the steam of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious injury and death.

134. Specifically, Xarelto was more likely to cause serious bleeding that may be irreversible, permanently disabling, and life-threatening than other anticoagulants.

135. Plaintiff used Xarelto in substantially the same condition it was in when it left the control of Defendants and any changes or modifications were foreseeable by Defendants.

136. Plaintiff and her healthcare providers did not misuse or materially alter her Xarelto.

137. As a direct and proximate result of the use of Xarelto, Plaintiff suffered serious physical injury (and in some cases death), harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

COUNT III
(DESIGN DEFECT)

138. 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.

139. Xarelto was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

140. Defendants placed Xarelto into the steam of commerce with wanton and reckless disregard for public safety.

141. Xarelto was in an unsafe, defective, and inherently dangerous condition.

142. Xarelto contains defects in its design which render the drug dangerous to consumers, such as Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render Xarelto more dangerous than other anticoagulants and cause an unreasonable increased risk of injury, including but not limited to life-threatening bleeding events.

143. Xarelto was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that Xarelto was defective and unsafe, even when used as instructed.

144. The nature and magnitude of the risk of harm associated with the design of Xarelto, including the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening is high in light of the intended and reasonably foreseeable use of Xarelto.

145. The risks of harm associated with the design of Xarelto are higher than necessary.

146. It is highly unlikely that Xarelto users would be aware of the risks associated with Xarelto through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks, nor would she expect them.

147. The design did not conform to any applicable public or private product standard that was in effect when Xarelto left the Defendants' control.

148. Xarelto's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

149. The intended or actual utility of Xarelto is not of such benefit to justify the risk of bleeding that may be irreversible, permanently disabling, and life-threatening.

150. At the time Xarelto left Defendants' control, it was both technically and economically feasible to have an alternative design that would not cause bleeding that may be irreversible, permanently disabling, and life-threatening or an alternative design that would have substantially reduced the risk of these injuries.

151. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

152. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

153. The unreasonably dangerous nature of Xarelto caused serious harm to Plaintiff.

154. As a direct and proximate result of the Plaintiff's use of the Xarelto, which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm (and in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

155. Plaintiff pleads this Count in this 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.

COUNT IV
(FAILURE TO WARN)

156. 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 possible, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

157. Defendants had a duty to warn Plaintiff and her healthcare providers regarding the need for blood monitoring, dose adjustments, twice daily dosing and failed to warn of the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening, associated with Xarelto.

158. Defendants knew, or in the exercise or reasonable care should have known, about the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening.

159. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening, in light of the likelihood that its product would cause these injuries.

160. Defendants failed to update warnings based on information received from product surveillance after Xarelto was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

161. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using Xarelto after FDA approval.

162. When it left Defendants' control, Xarelto was defective and unreasonably dangerous for failing to warn of the risk of serious bleeding that may be irreversible, permanently disabling, and life-threatening.

163. Plaintiff used Xarelto for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

164. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

165. Defendants, as the manufacturers and distributors of Xarelto, are held to the level of knowledge of an expert in the field.

166. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

167. The warnings that were given by the Defendants failed to properly warn physicians of the risk associated with Xarelto, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

168. Defendants had a continuing duty to warn Plaintiff and her prescriber of the dangers associated with its product.

169. Had Plaintiff or her healthcare providers received adequate warnings regarding the risks associated with the use of Xarelto, they would not have used it or they would have used it with blood monitoring.

170. The Plaintiff's injuries (including and in some cases death), were the direct and proximate result of Defendants' failure to warn of the dangers of Xarelto.

171. Defendants' conduct, as described above, was extreme and outrageous. Defendants risks the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT V
(NEGLIGENCE)

172. 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.

173. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Xarelto including a duty to assure that the product did not cause unreasonable, dangerous side-effects to users.

174. Defendants failed to exercise ordinary care in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Xarelto in that Defendants knew, or should have known, that the drugs created a high risk of unreasonable, dangerous side-effects and harm, including life-threatening bleeding, as well as other severe and personal injuries (including in some cases death) which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

175. Defendants, their agents, servants, and/or employees were negligent in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and sale, distribution of Xarelto in that, among other things, they:

a. Failed to use due care in designing and manufacturing, and testing Xarelto so as to avoid the aforementioned risks to individuals;

b. Failed to analyze pre-marketing test data of Xarelto;

c. Failed to conduct sufficient post-marketing and surveillance of Xarelto;

d. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects; the warnings given did not warn Plaintiff 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;

e. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Xarelto;

f. Falsely and misleadingly overpromoted, advertised and marketed Xarelto as set forth herein including overstating efficacy, minimizing risk and stating that blood monitoring and dose adjustments were not necessary for safe and effective use to influence patients, such as Plaintiff, to purchase and consume such product;

g. Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without thoroughly testing it;

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

i. 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;

j. Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;

k. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;

l. 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;

m. Failing to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto;

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

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

p. 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;

q. Negligently designing Xarelto in a manner which was dangerous to its users;

r. Negligently manufacturing Xarelto in a manner which was dangerous to its users;

s. Negligently producing Xarelto in a manner which was dangerous to its users;

t. Negligently assembling Xarelto in a manner which was dangerous to its users;

u. Concealing information from the Plaintiff in knowing that Xarelto was unsafe, dangerous, and/or non-confirming with FDA regulations;

v. Improperly concealing and/or mispresenting 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; and,

w. Placing an unsafe product into the stream of commerce.

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

177. 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.

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

a. Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with 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 or potentially serious side effects;

h. Were otherwise careless and/or negligent.

179. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market Xarelto to consumers, including the medical community and Plaintiff.

180. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

181. It was foreseeable that Defendants' product, as designed, would cause serious injury to consumers, including Plaintiff.

182. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm (and in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

183. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VI
(BREACH OF EXPRESS WARRANTY)

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

185. Defendants expressly warranted that Xarelto was safe and effective to members of the consuming public, including Plaintiff.

186. Defendants expressly warranted that Xarelto was a safe and effective product to be used as a blood thinner, and did not disclose the material risks that Xarelto could cause serious bleeding that may be irreversible, permanently disabling, and life-threatening. The representations were not justified by the performance of Xarelto.

187. Defendants expressly warranted Xarelto was safe and effective to use without the need for blood monitoring and dose adjustments.

188. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, 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.

189. 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.

190. Plaintiff and her healthcare providers reasonably relied on these express representations.

191. Xarelto does not conform to these express representations because Xarelto is not safe and has serious side-effects, including death.

192. Defendants breached their express warranty in one or more of the following ways:

a. Xarelto as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on Xarelto;

c. Defendants failed to adequately test Xarelto; and,

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Xarelto.

193. Plaintiff reasonably relied upon Defendants' warranty that Xarelto was safe and effective when she purchased and used the medications.

194. Defendants herein breached the aforesaid express warranties as their drug was defective.

195. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

196. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VII
(BREACH OF IMPLIED WARRANTY)

197. 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.

198. At the time Defendants marketed, distributed and sold Xarelto to Plaintiff, Defendants warranted that Xarelto was merchantable and fit for the ordinary purposes for which it was intended.

199. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

200. Xarelto was not merchantable and fit for its ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this Complaint.

201. Plaintiff reasonably relied on Defendants' representations that Xarelto was safe and free of defects and was a safe means of reducing 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.

202. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injury.

203. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VIII
(NEGLIGENT MISREPRESENTATION)

204. 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 the law principles, regardless of whether arising under statute and/or common law.

205. From the time Xarelto was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made

misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Xarelto was safe, fit and effective for human use. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale of Xarelto and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of Xarelto.

206. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase, and use of Xarelto.

207. The representations by the Defendants were in fact false, in that Xarelto is not safe, fit and effective for human consumption as labeled, using Xarelto is hazardous to your health, and Xarelto has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

208. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase, and use of Xarelto.

209. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use Xarelto. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used Xarelto. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

210. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

COUNT IX
(FRAUD)

211. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count for fraud and deception in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's residence State and Cal. Civ. Code §§ 1709, 1710.

212. Prior to Plaintiff's use of Xarelto and during the period in which Plaintiff 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. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Xarelto strong.

213. The Defendants falsely and fraudulently represented 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 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.

214. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in

particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

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

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

217. 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.

218. 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.

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

220. 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 Plaintiff, to purchase and use Xarelto.

221. At the time Defendants concealed the fact that Xarelto was not safe, Defendants were under a duty to communicate this information to Plaintiff, physicians, the FDA, the healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Xarelto.

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

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

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

225. Xarelto was improperly marketed to the Plaintiff 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.

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

227. In is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiff. 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.

228. Defendants' fraud also acted to conceal their malfeasance which actions tolled 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 Plaintiff, her prescribing physicians, the healthcare community and the general public. Without full knowledge of the dangers of Xarelto, Plaintiff could not evaluate whether a person who was injured by Xarelto had a valid claim.

229. 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.

230. 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 Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and consume Xarelto.

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

232. 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 Plaintiff, to purchase Defendants' dangerous product.

233. Had Plaintiff been aware of the hazards associated with Xarelto, Plaintiff 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 Plaintiff's injuries.

234. 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 Plaintiff, from discovering these hazards.

COUNT X
(VIOLATION OF CONSUMER PROTECTION LAWS/CONSUMER FRAUD LAWS)
A.R.S. §§ 44-1521-1534
Cal. Civ. Code §§ 1750-1785 & Consumers Legal Remedies Act)

235. 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.

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

237. 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.

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

239. Defendants violated consumer protection laws of various states.

240. 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 Plaintiff, in the marketing and advertising campaign described herein.

241. 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.

242. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur; serious physical injury, 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.

VI. JURY TRIAL DEMANDED

Plaintiff demands that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

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

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Postjudgment interest;

6. Awarding Plaintiff reasonable attorneys' fees when applicable;

7. Awarding Plaintiff the cost of these proceedings; and

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

Dated: February 18, 2016

Respectfully submitted,

_____

Deborah S. Kerr
GOLDBERG & OSBORNE
915 W. Camelback Road
Phoenix, AZ 85013
Telephone: (602) 808-6750
Facsimile: (602) 808-6799
E-mail: dkerr@goldbergandosborne.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on February ____, 2016, I electronically filed the foregoing Complaint with the Clerk of the Court using the CM/ECF system, which will notify al attorneys of record of such filing.

_____

Deborah S. Kerr

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

Garvy, Margaret M.

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

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

Deborah S. Kerr, Esq. Goldberg & Osborne
915 W. Camelback Road, Phoenix, AZ 85013 (602) 808-6750

DEFENDANTS

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

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

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

Attorneys *(If Known)*

Drinker Biddle & Reath LLP
600 Campus Drive, Florham Park, NJ 07932-1047
(973) 549-7000

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

TORTS

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

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

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

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

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

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

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

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

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

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

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

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

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

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 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 U.S.C. 1332 - Plaintiff & Defendants are citizens of different states; amount in controversy exceeds $75,000.

Brief description of cause:
Ingestion of the drug Xarelto causing harmful bleed

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 Judge Eldon E. Fallon DOCKET NUMBER MDL NO. 2592

DATE 02/18/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ Deborah S. Kerr

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset

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

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Pharma AG
Muellerstrasse, 178, D-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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Corporation
Corporation Service Company
251 East Ohio Street, Suite 500
Indianapolis, IN 46204

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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BAYER HEALTHCARE AG
CHEMPARK Leverkusen
Zentraler Besucherempfang
D-51368 Leverkusen
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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Healthcare, LLC
Corporation Service Company
2711 Centerville Road, Suite 400
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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BAYER HEALTHCARE PHARMACEUTICALS, INC.
SOP Department
Corporation Service Company
2711 Centerville Road, Suite 400
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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Pharma AG
Muellerstrasse, 178, D-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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Ortho, LLC
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharmaceuticals, Inc.
f/k/a Jansseen Pharmaceutica Inc.
f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.
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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research & Development LLC
f/k/a Johnson and Johnson Pharmaceutical
Research and 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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

MARGARET M. GARVY

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACETICAL RESEARCH AND DEVELOPMENT LLC, et al

Defendant(s)

MDL NO. 2592
PRODUCTS LIABILITY LITIGATION
SECTION L
JUDGE ELDON E. FALLON
MAG. JUDGE NORTH

Civil Action No. 2:16-cv-1359

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson Company
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:

Deborah S. Kerr
Goldberg & Osborne
915 West Camelback Road
Phoenix, Arizona 85013
dkerr@goldbergandosborne.com

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. 2:16-cv-1359

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:

Print Save As... Reset