UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

MOLLY ANN HARR and DANIEL HARR, JR., h/w, ***Plaintiffs,*** **v.** **JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG,** ***Defendants.***	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Case No. 1:15-cv-647**

COMPLAINT

Plaintiff, Molly Ann Harr and Daniel Harr, Jr., by and through the undersigned counsel, through their Complaint hereby allege against JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG, the following:

I. THE PARTIES

A. PLAINTIFF

1. At all times relevant times hereto, Plaintiff, Molly Ann Harr ("Plaintiff"), was a resident and citizen of Mount Gilead, Morrow County, Ohio.

2. At all times relevant hereto, Plaintiff, Daniel Harr, Jr., was the husband of Plaintiff, Molly Ann Harr, and a resident and citizen of Mount Gilead, Morrow County, Ohio.

3. Plaintiff was prescribed Xarelto (rivaroxaban) for the treatment of chronic atrial fibrillation, and suffered serious and life-threatening injuries including gastrointestinal bleeding, anemia, and mental anguish, as well as other severe and personal injuries which are permanent and lasting in nature, including, but not limited to, diminished enjoyment of life, expenses for hospitalization and medical treatment, and other economic and non-economic damages.

B. DEFENDANTS

4. Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

5. Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a

principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

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

7. 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. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

8. Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective

December 29, 2006. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

9. Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

10. Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC. At all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto.

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

12. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany. Defendant BAYER AG is the third largest pharmaceutical company in the world. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

13. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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.

14. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

15. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, labeling, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the Commonwealth of Pennsylvania, either directly or indirectly through third parties, subsidiaries or related entities, Xarelto.

II. JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of Florida, which is different from the states where Defendants are incorporated and have their principal places of business.

17. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

III. FACTUAL ALLEGATIONS

A. NATURE OF THE CASE

19. At all times relevant hereto, Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "Defendants"), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

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

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

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

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

24. 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.

25. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition),

accompanied by similar rates of bleeding. However, the studies also showed a greater incidence with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty*. N.Engl.J.Med. 2008;358:2776-86; Kakkar, A.K., et al. *Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial*. Lancet 2008;372:31-39; Ericksson, B.I., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty*. N.Engl.J.Med. 2008;358:2765-75.)

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

27. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for

treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism*. N.Engl.J.Med. 2010;363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. *Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study)*. Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN-PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N.Engl.J.Med. 2012;366:1287-97.)

28. 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.

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

30. However, in its QuarterWatch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval

process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing."

31. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

32. Defendants spent significant money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

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

34. 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.

35. During the Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

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

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

38. 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.

39. Upon information and belief, prior to Plaintiff's prescription of Xarelto, Plaintiff became aware of the promotional materials described herein.

40. Upon information and belief, prior to Plaintiff's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also

adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

41. 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.

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

43. 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.

44. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

45. 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."

46. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

50. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 104 (a – o).

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

52. 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.

53. 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.

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

55. Upon information and belief, Defendants ignored the association between the use of Xarelto and the risk of suffering life-threatening bleeding events.

56. At all times relevant hereto, when warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to

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

57. At all times relevant hereto, Defendants concealed their knowledge of Xarelto's defects from Plaintiff, the FDA, the public in general, and/or the medical community specifically. These representations were made by Defendants with the intent of defrauding and deceiving 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 community in particular, to recommend, dispense and/or purchase Xarelto for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

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

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

60. In or around September 2013, Plaintiff was prescribed and began taking Xarelto upon direction of her physician for the treatment of chronic atrial fibrillation.

61. As a direct and proximate result of the use of Defendants' Xarelto, Plaintiff experienced gastrointestinal bleeding and anemia and was hospitalized on or about November 27, 2013.

62. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including inter alia life-threatening gastrointestinal bleeding anemia, coagulopathy, and physical pain as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of Xarelto.

63. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Xarelto, which has caused Plaintiff to suffer from life-threatening gastrointestinal bleeding, anemia, and coagulopathy, as well as other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

64. By reason of the foregoing acts and omissions, Plaintiff has endured and continues to suffer emotional and mental anguish, loss of accumulations, medical expenses, and other economic and non-economic damages, as a result of the actions and inactions of the Defendants.

65. The subject product ingested by Plaintiff, and which proximately caused his injury, pain and suffering, was designed, manufactured, packaged, labeled, and placed into the stream of interstate commerce by Defendants.

66. The Defendants are joint tortfeasors, jointly and severally liable to Plaintiff for his injuries.

B. FEDERAL STANDARDS AND REQUIREMENTS

67. Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of their product, Xarelto, including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations.

IV. CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY

68. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

70. Defendants' Xarelto ingested by Plaintiff was in the same or substantially similar condition as when they left the possession of Defendants.

71. Plaintiff did not misuse or materially alter the Xarelto she ingested.

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

a. Defendants' 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 the Xarelto products;

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. Defendants failed to market a feasible alternative design that existed that was capable of preventing Plaintiff's injuries.

73. Defendants' actions and omissions were the direct and proximate cause of Plaintiff's injuries.

74. 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 which was wanton and willful warrants an award of punitive damages.

75. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

76. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

77. 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.

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

79. Defendants' Xarelto was not merchantable and fit for its ordinary purpose, because it had a propensity to lead to the serious personal injuries as described herein in this Complaint.

80. Plaintiff reasonably relied on Defendants' representations that Xarelto was safe and free of defects and was a safe means of treating deep vein thrombosis and pulmonary embolism, which she was suffering.

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

82. 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.

83. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

84. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

85. Defendants manufactured, supplied and sold Xarelto with an implied warranty that it was fit for the particular purpose of a safe means to treat atrial fibrillation.

86. Members of the consuming public, including Plaintiff, were the intended third-party beneficiaries of the warranty.

87. Defendants' Xarelto was not fit for the particular purpose as a safe means of treating atrial fibrillation, which risk is much higher than other anticoagulants.

88. Plaintiff reasonably relied on Defendants' representations that Xarelto was safe and effective for treating atrial fibrillation.

89. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiff's injuries.

90. 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.

91. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENT FAILURE TO WARN

92. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully herein.

93. Before Plaintiff ingested Xarelto, and during the period in which she took the medication, Defendants knew or had reason to know that Xarelto was dangerous and created an unreasonable risk of bodily harm to consumers.

94. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Xarelto likely to be dangerous.

95. Despite the fact that Defendants knew or had reason to know that Xarelto was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Xarelto likely to be dangerous.

96. Plaintiff's injuries were the direct and proximate result of Defendants' failure to warn of the dangers of Xarelto.

97. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked 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.

98. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT DESIGN DEFECT

99. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

100. Defendants are the manufacturer, seller, distributor, marketer, and supplier of Xarelto which was negligently designed.

101. Defendants failed to exercise reasonable care in designing, developing, formulating, manufacturing, inspecting, testing, packaging, selling, distributing, labeling,

marketing, and promoting Xarelto which was defective and presented an unreasonable risk of harm to consumers, such as Plaintiff.

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

103. Plaintiff ingested Xarelto in a reasonably foreseeable manner, and substantially as intended by Defendants.

104. Defendants' Xarelto was not materially altered or modified after manufactured by Defendants and before taken by Plaintiff.

105. The design defects directly rendered Xarelto defective and was the direct and proximate result of Defendants' negligence and failure to use reasonable care in designing, testing, and manufacturing Xarelto.

106. As a direct and proximate result of Defendants' negligent design of Xarelto, Plaintiff suffered injury.

107. Despite the fact that Defendants knew or should have known that Xarelto was defectively designed, contained design defects, and caused an unreasonable risk of harm, Defendants designed, manufactured, sold, and marketed Xarelto to consumers, including the medical community and Plaintiff, and failed to warn consumers, the medical community, and Plaintiff of the increased risk of harm relative to other anticoagulants.

108. 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.

109. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE

110. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

111. Defendants had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of Xarelto, including a duty to assure that the product did not cause unreasonable, dangerous side-effects to users.

112. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, distribution, advertising, promotion, sale and marketing of Xarelto in that Defendants knew or should have known that the drug created a high risk of unreasonable harm.

113. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Xarelto in that, among other things, they:

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

b. 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;

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

d. Placed an unsafe product into the stream of commerce;

e. Over-promoted Xarelto and marketed, and advertised the drug in a manner that minimized the risks and damages of the drug; and,

f. Were otherwise careless or negligent.

114. 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.

115. 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.

116. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

117. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

118. Prior to Plaintiff's use of Xarelto and during the period in which she took Xarelto, Defendants misrepresented that Xarelto was a safe and effective anticoagulant medication.

119. Defendants also failed to disclose material facts regarding the safety and efficacy of Xarelto, including information regarding increased adverse events and harmful side-effects.

120. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of Xarelto they marketed, distributed and sold.

121. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with Xarelto that their representations regarding Xarelto were false, and that they had a duty to disclose the dangers of Xarelto.

122. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by using Xarelto.

123. Plaintiff justifiably relied on Defendants' representations and nondisclosures by using Xarelto.

124. Defendants' misrepresentations and omissions regarding the safety and efficacy of Xarelto was the direct and proximate cause of Plaintiff's injuries.

125. 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.

126. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

127. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

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

130. Defendants marketed, promoted and sold Xarelto as a safe product.

131. Xarelto does not conform to these express representations because it is not safe and has serious side-effects, including life-threatening and irreversible bleeding events.

132. 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 Xarleto.

133. Plaintiff reasonably relied upon Defendants' warranty that Xarelto was safe and effective when she took the medication.

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

135. 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.

136. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
FRAUD

137. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

138. Prior to Plaintiff's ingestion of Xarelto and during the period in which Plaintiff was actually taking Xarelto, Defendants fraudulently suppressed material information regarding the safety and efficacy of Xarelto, including information regarding the risk of life-threatening bleeding events. Furthermore, Defendants fraudulently concealed the safety information about the use of Xarelto. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to maintain and support the sales volume of Xarelto.

139. Defendants fraudulently concealed the safety issues associated with Xarelto in order to induce physicians to recommend its use to patient's families, including Plaintiff.

140. 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 Xarelto.

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

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

143. Plaintiff and his physicians were not provided with the necessary information by the Defendants, to provide an adequate warning to the Plaintiff.

144. Xarelto was improperly marketed to Plaintiff and his physicians as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the medications' risks.

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

146. It 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.

147. Defendants widely advertised and promoted Xarelto as a safe and effective anticoagulant medication and/or as a safe and effective means of treating atrial fibrillation.

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

149. 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.

150. Had Plaintiff been aware of the hazards associated with Xarelto, Plaintiff would not have taken the product which led proximately to Plaintiff's adverse health effects, including his life-threatening bleeding event.

151. Defendants' advertisements regarding Xarelto made material misrepresentations to the effect that Xarelto was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such products. Plaintiff relied on these material misrepresentations when deciding to take Xarelto.

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

153. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
VIOLATION OF CONSUMER PROTECTION LAWS

154. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

155. Plaintiff purchased and used Xarelto primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

156. 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.

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

158. 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 its 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 Plaintiffs in the marketing and advertising campaign described herein.

159. 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.

160. 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.

161. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
FRAUDULENT CONCEALMENT

162. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

163. Prior to Plaintiff's use of Xarelto and during the period in which Plaintiff actually used the Xarelto, Defendants fraudulently suppressed material information regarding the safety

and efficacy of Xarelto and the availability of an alternative feasible safer design, as described in this Complaint. Furthermore, Defendants fraudulently concealed the safety information about the use of Xarelto. Plaintiff believes the fraudulent misrepresentations and fraudulent concealment described throughout this Complaint was intentional so as to maintain the sales volume of Xarelto strong, particularly in the face of new competition from other anticoagulants.

164. Defendants intentionally concealed safety issues with Xarelto in order to induce physicians to recommend to patients, including Plaintiff, to use Xarelto.

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

166. Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety, and dosing for the use of Xarelto.

167. As a direct and proximate cause of Defendants' malicious and intentional concealment of material and information, Defendants caused or significantly contributed to Plaintiff's injuries.

168. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, properly label, warn or inform the unsuspecting and consuming public. Defendants' outrageous conduct rises to the level that is appropriate that entitles Plaintiff to an award of 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.

169. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Xarelto as described herein, and Defendants did not disclose this information to the Plaintiff, doctors generally, 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.

170. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XII
LOSS OF CONSORTIUM, COMPANIONSHIP, SERVICES

171. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

172. Plaintiff, Daniel Harr, Jr., as the husband of Molly Ann Harr, claims loss of consortium, companionship, services, obligation for medical expenses to the broadest extent available under the law, pleading same pursuant to all substantive law that applies to this case, including but not limited to the law of the State of Ohio, as may be determined by choice of law principles regardless of those arising under statute and/or common law.

DISCOVERY RULE AND TOLLING

173. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Complaint and

Jury Demand in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

174. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

175. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

176. Despite diligent investigation by Plaintiffs into the cause of their injuries the nature of Plaintiffs' injuries and damages, and their relationship to Xarelto was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

177. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and/or Plaintiffs' physicians of the true risks associated with the Products. As a result of the Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PUNITIVE DAMAGES ALLEGATIONS

178. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

179. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Xarelto users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Xarelto. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

180. Prior to the manufacturing, sale, and distribution of Xarelto, Defendants knew that Xarelto was in defective conditions as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Xarelto.

181. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Xarelto and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Xarelto. Defendants and

their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Xarelto knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

182. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiffs respectfully request an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

V. JURY TRIAL DEMANDED

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

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, for damages, including exemplary damages if applicable, to which they are entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. judgment for Plaintiff and against Defendants, jointly and severally;

b. damages to compensate Plaintiff for injuries sustained by the Plaintiff as a result of the use of Xarelto;

c. damages for Plaintiff's past and future loss of income;

d. damages to compensate Plaintiff for the physical pain and suffering of the Plaintiff;

e. pre and post judgment interest at the lawful rate;

f. exemplary, punitive and treble on all applicable Counts as permitted by the law;

g. a trial by jury on all issues of the case;

h. an award of attorneys' fees; and

i. for any other relief as this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all reliefs prayed for in this Complaint and in the forgoing Prayer for Relief.

Respectfully submitted,

/s/ Michelle L. Kranz
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Attorneys for Plaintiffs

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

Molly Ann Harr and Daniel Harr, Jr., h/w

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michelle L. Kranz, Esq., Zoll & Kranz, LLC
6620 W. Central Ave., Ste. 100
Toledo, OH 43617 (419) 841-9623

DEFENDANTS

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

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

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

Attorneys *(If Known)*

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

- ❒ 1 U.S. Government Plaintiff
- ❒ 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)*

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- ❒ 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

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

TORTS

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

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

PERSONAL PROPERTY
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- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
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- ❒ 446 Amer. w/Disabilities - Other
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Other:
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- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

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- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

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- ❒ 720 Labor/Management Relations
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- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

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- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal injury/products liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Eldon E. Fallon DOCKET NUMBER 2:14-md-02592

DATE
10/05/2015

SIGNATURE OF ATTORNEY OF RECORD
/s/ Michelle L. Kranz

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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