JOINT COMPLAINT – REVISED DRAFT (JANUARY, 2016)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ANDY APPLE, BRIAN BARNONE, CANDY CORN, DONNA DIXON, ELLEN ELKIN, FRED FINKEL, AND GEAUX GIROD 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., 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**

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JOINT COMPLAINT

Pursuant to Pretrial Order No. 11**,** Plaintiffs, by and through counsel, file this *Joint Complaint* against Defendants, as follows:

I. PLAINTIFF SPECIFIC ALLEGATIONS [NOTE: PTO 11(1)(b)][1]

Plaintiffs herein are: [list each plaintiff alphabetically and add counts necessary and appropriate for each client specific jurisdiction, if necessary]

1. Andy Apple [include county & state of citizenship for each plaintiff]

    a. Plaintiff, _____, ingested Xarelto from approximately _____ to ____ and suffered a gastrointestinal bleed on ____ as a direct result of Xarelto. Plaintiff _____ resides in _____ County in the state of_____.

[1] **THROUGHOUT THIS DOCUMENT A NUMBER OF ITEMS ARE HIGHLIGHTED IN YELLOW. THESE HIGHLIGHTED AREAS ARE MEANT TO PROVIDE GUIDANCE TO INDIVIDUAL COUNSEL SO THAT INDIVIDUAL COUNSEL CAN SPECIFICALLY PREPARE ITS CLIENT'S COMPLAINT. IN ADDITION, THE CLAIMANTS IDENTIFIED IN SECTION I. PLAINTIFF SPECIFIC ALLEGATIONS ARE FICTIOUS NAMES THAT SHOULD BE REMOVED AND ARE PLACED WITHIN SOLELY AS EXAMPLES. COUNSEL ARE IN INSTRUCTED TO EDIT THE PLEADING THEY USE FOR THEIR PARTICULAR CLIENTS APPROPRIATELY BY REMOVING THE DISCLAIMER IN THE FOOTER BELOW, YELLOW HIGHLIGHTING AND INSTRUCTIONS. COUNSEL ARE ALSO INSTRUCTED TO FILL-IN OR DELETE BLANKS AS APPROPRIATE.**

2. Brian Barnone [use if claim includes loss of consortium]

   a. Plaintiff, Brian Barnone, ingested Xarelto from approximately _____ to ____ and suffered a gastrointestinal bleed on ____ as a direct result of Xarelto. Plaintiff _____ resides in _____ County in the state of_____.

   b. In conjunction with Plaintiff Barnone's claim, Belinda Barnone, spouse of Brian Barnone, asserts a claim for loss of consortium.

3. Candy Corn [use if minor]

   a. Plaintiff, _____, a minor, ingested Xarelto from approximately ____ to __ and suffered severe internal bleeding on _____ as a direct result of Xarelto. Plaintiff _____ resides in ___ County in the state of _____. Plaintiff _____ is represented herein by his guardian(s), _____.

4. Donna Dixon [use if death case]

   a. Plaintiff, _____, ingested Xarelto from approximately ____ to __ and suffered severe internal bleeding on _____ as a direct result of Xarelto. Plaintiff _____ ultimately died due to his injuries on _____. Plaintiff

_____ was a resident of ___ County in the state of _____. Plaintiff _____ is represented herein by ____, the executor of his estate.

5. Ellen Elkin [use if state of death is different from state of citizenship]

   a. Plaintiff, _____, ingested Xarelto from approximately ____ to __ and suffered severe internal bleeding on _____ as a direct result of Xarelto. Plaintiff _____ ultimately died due to his injuries on _____ in _____ county in the state of _____. Plaintiff _____ was a resident of ___ County in the state of _____ at the time of his death. Plaintiff _____ is represented herein by ____, the executor of his estate.

6. Fred Finkel [use if location of injury & ingestion are different from state of current citizenship]

   a. Plaintiff, _____, ingested Xarelto from approximately _____ to ____ and suffered a gastrointestinal bleed on ____ as a direct result of Xarelto. Plaintiff _____ resides in _____ County in the state of_____. At the time of the ingestion and injury Plaintiff resided in _____ County in the state of _____.

7. Geaux Girod [use if state of injury, ingestion and current citizenship are all different]

a. Plaintiff, _____, ingested Xarelto from approximately _____ to ____ and suffered brain hemorrhaging on ____ as a direct result of Xarelto. Plaintiff _____ currently resides in _____ County in the state of_____. At the time of the ingestion Plaintiff resided in _____ County in the state of _____. At the time of injury Plaintiff resided in ____ County in the state of _____.

II. DEFENDANTS

8. 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.

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

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

11. 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.

12. 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.

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

14. 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.

15. 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.

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

17. 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.

18. 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.

19. 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.

20. 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.

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

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

24. 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.

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

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

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

28. 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.

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

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

31. 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.

32. 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 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.

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

34. 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.

35. 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.

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

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

38. 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.

39. 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."

40. 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.

41. 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.

42. 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

43. 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 Plaintiffs and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

44. 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.

45. A substantial part of the events and omissions giving rise to Plaintiffs' 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.

46. 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

47. Plaintiffs bring 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, Plaintiffs 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 their use of Xarelto.

48. 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.

49. 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").

50. 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.

51. 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.

52. 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).

53. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that Xarelto was superior (based on the Defendants' definition) to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty, accompanied by similar rates of bleeding. However, the studies also showed a greater bleeding incidence with Xarelto leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al.

Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty. N. Engl. J. Med. 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomized controlled trial. Lancet 2008; 372:31-39; Ericksson, B.I., et al. Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty. N. Engl. J. Med. 2008; 358:2765-75.).

54. 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)).

55. 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").

56. 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.)

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.)

66. 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.

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

68. 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."

69. 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.

70. 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."

71. 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.

72. 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.

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

74. 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.

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

76. 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."

77. 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.

78. 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.

79. 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.

80. 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 Plaintiffs' 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.

81. 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).

82. 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

83. 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.

84. 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.

85. 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.

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

87. 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.

88. 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.

89. 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.

90. 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.

91. 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.

92. Prior to Plaintiffs' ingestion of Xarelto, Plaintiffs became aware of the promotional materials described herein.

93. Prior to Plaintiffs' prescription of Xarelto, Plaintiffs' 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.

94. 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.

95. 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.

96. Prior to applying to the FDA for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical

scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

97. As a result of Defendants' claim regarding the effectiveness and safety of Xarelto, Plaintiffs' medical providers prescribed and Plaintiffs ingested Xarelto.

C. The Plaintiffs' Use of Xarelto and Resulting Injuries

98. By reason of the foregoing acts and omissions, Plaintiffs were 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.

99. 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.

100. 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 Plaintiffs' prescribing physicians or Plaintiffs 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.

101. 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.

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

103. Upon information and belief, Defendants failed to warn Plaintiffs and their 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.

104. 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.

105. 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 Plaintiffs from discovering, and/or with reasonable diligence being able to discover, their causes of action.

106. 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.

107. By reason of the forgoing acts and omissions, Plaintiffs have 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)

108. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead 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 Plaintiffs' resident State.

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

110. 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.

111. 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.

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

113. 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.

114. 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.

115. 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.

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

117. At the time of the Plaintiffs' 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.

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

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

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

121. 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.

122. 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.

123. 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 Plaintiffs in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiffs.

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

125. 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.

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

127. 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.

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

129. Plaintiffs did not misuse or materially alter their Xarelto.

130. Defendants are strictly liable for Plaintiffs' 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 Plaintiffs' injuries.

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

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

133. That said defects in Defendants' drug Xarelto were a substantial factor in causing Plaintiffs' injuries.

134. As a result of the foregoing acts and omissions, Plaintiffs were 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.

135. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs,

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)

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

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

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

139. Xarelto was defective when it left Defendants' control and was placed in the stream 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.

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

141. Plaintiffs 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.

142. Plaintiffs and their healthcare providers did not misuse or materially alter their Xarelto.

143. As a direct and proximate result of the use of Xarelto, Plaintiffs' 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)

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

145. 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 Plaintiffs.

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

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

148. Xarelto contains defects in its design which render the drug dangerous to consumers, such as Plaintiffs, 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.

149. 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.

150. 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.

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

152. It is highly unlikely that Xarelto users would be aware of the risks associated with Xarelto through either warnings, general knowledge or otherwise, and Plaintiffs specifically were not aware of these risks, nor would they expect them.

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

154. 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 Plaintiffs expected.

155. 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.

156. 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.

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

158. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, 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.

159. The unreasonably dangerous nature of Xarelto caused serious harm to Plaintiffs.

160. As a direct and proximate result of the Plaintiffs' use of the Xarelto, which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce

by Defendants, Plaintiffs 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.

161. Plaintiffs plead 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.

COUNT IV
(FAILURE TO WARN)

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

163. Defendants had a duty to warn Plaintiffs and their 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.

164. 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.

165. 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.

166. 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.

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

168. 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.

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

170. Plaintiffs and Plaintiffs' 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.

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

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

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

174. Defendants had a continuing duty to warn Plaintiffs and their prescriber of the dangers associated with its product.

175. Had Plaintiffs or their 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.

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

177. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, 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)

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

179. 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.

180. 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.

181. 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 Plaintiffs and their 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 Plaintiffs, 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 Plaintiffs, 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 Plaintiffs in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations;

v. Improperly concealing and/or misrepresenting information from the Plaintiffs, 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.

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

183. 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.

184. 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 Plaintiffs 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 Plaintiffs, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

h. Were otherwise careless and/or negligent.

185. 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 Plaintiffs.

186. Defendants knew or should have known that consumers such as the Plaintiffs 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.

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

188. As a direct and proximate result of Defendants' negligence, Plaintiffs 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.

189. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, 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)

190. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count 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.

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

192. 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.

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

194. Defendants expressly represented to Plaintiffs, Plaintiffs' 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.

195. 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.

196. Plaintiffs and their healthcare providers reasonably relied on these express representations.

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

198. 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.

199. Plaintiffs reasonably relied upon Defendants' warranty that Xarelto was safe and effective when they purchased and used the medication.

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

201. Plaintiffs' injuries (and in some cases death) were the direct and proximate result of Defendants' breach of their express warranty.

202. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, 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)

203. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense available

under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

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

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

206. 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.

207. Plaintiffs 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.

208. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injury (including in some cases death).

209. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, 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)

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

211. From the time Xarelto was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiffs, Plaintiffs' 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 Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of Xarelto.

212. 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.

213. 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 Plaintiffs.

214. 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.

215. In reliance on the misrepresentations by the Defendants, Plaintiffs were induced to purchase and use Xarelto. If Plaintiffs had known the truth and the facts concealed by the Defendants, Plaintiffs would not have used Xarelto. The reliance of Plaintiffs 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.

216. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiffs suffered injuries (including, in some cases, death) and damages as alleged herein.

COUNT IX
(FRAUD)

217. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count 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.

218. Prior to Plaintiffs' use of Xarelto and during the period in which Plaintiffs 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. Plaintiffs believe that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Xarelto strong.

219. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiffs, 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.

220. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiffs, 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 Plaintiffs herein.

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

222. In reliance upon said representations, Plaintiffs were induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

223. 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.

224. 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.

225. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiffs.

226. 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 Plaintiffs, to purchase and use Xarelto.

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

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

229. Plaintiffs and the Plaintiffs' prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of Xarelto.

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

231. Xarelto was improperly marketed to the Plaintiffs and their 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.

232. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiffs and Plaintiffs' prescribing physicians, Defendants caused or contributed to Plaintiffs' injuries (and in some cases death).

233. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiffs. 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 Plaintiffs 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.

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

235. 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.

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

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

238. 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 Plaintiffs, to purchase Defendants' dangerous product.

239. Had Plaintiffs been aware of the hazards associated with Xarelto, Plaintiffs 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 Plaintiffs' injuries (including in some cases death).

240. Upon information and belief, Plaintiffs aver 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 Plaintiffs, from discovering these hazards.

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

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

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

243. 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.

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

245. Defendants violated consumer protection laws of various states.

246. 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 Plaintiffs, in the marketing and advertising campaign described herein.

247. 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.

248. As a result of these violations of consumer protection laws, Plaintiffs have incurred and will incur; serious physical injury (including in some cases death), pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

COUNT XI
(LOSS OF CONSORTIUM)

249. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count 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.

250. At all relevant times hereto, where applicable, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Plaintiffs' injuries from Xarelto.

251. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

252. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

253. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

254. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

255. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable

damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

COUNT XII
(WRONGFUL DEATH)

256. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count 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.

257. Plaintiffs bring this claim, where appropriate, on behalf of the Estate and for the benefit of the Plaintiff Decedents' lawful beneficiaries.

258. As a direct and proximate result of the conduct of the Defendants and the defective nature of Xarelto as outlined above, Plaintiff Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment

of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

259. As a direct and proximate cause of the conduct of Defendants, Plaintiff Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses under applicable state statutory and/or common laws.

COUNT XIII
(SURVIVAL ACTION)

260. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count 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.

261. As a direct and proximate result of the conduct of Defendants, where appropriate, Plaintiff Decedents, prior to their death, were obligated to spend various sums of money to treat his or her injuries, which debts have been assumed by the Estate. As a direct and proximate

cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of his or her death; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs bring this claim on behalf of Decedents' estates under applicable state statutory and/or common laws.

262. As a direct and proximate result of the conduct of Defendants, Plaintiff Decedents and their spouses and heirs, including domestic partners, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder.

263. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Plaintiff Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses or heirs, including domestic partners, as Administrators or beneficiaries of the estate of the Decedent, bring the

claim on behalf of the estate for damages under applicable statutory and/or common laws, and in their own right.

COUNT XIV
(STATE SPECIFIC ALLEGATIONS)

264. Counsel may want to include specific state specific allegations applicable to certain plaintiffs depending upon the particular jurisdiction of the particular plaintiff. This determination is the responsibility of individually retained counsel. Allegations should be plead as appropriate. Also state specific allegations should be cross-referenced to the particular plaintiff identified in Section I. PLAINTIF SPECIFIC ALLEGATIONS above.

VI. 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.

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 determine 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 costs of these proceedings; and

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

Respectfully submitted,

[INDIVIDUAL COUNSEL SIGNATURE BLOCK]