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ATTORNEYS FOR PLAINTIFF

IN RE: XARELTO® LITIGATION [redacted]	:	**COURT OF COMMON PLEAS PHILADELPHIA COUNTY TRIAL DIVISION**
[redacted] **Plaintiff**	:	**COURT OF COMMON PLEAS PHILADELPHIA COUNTY**
v.	:	**MARCH TERM, 2015 DOCKET NO. _____**
JANSSEN RESEARCH & DEVELOPMENT, LLC f/k/a JOHNSON AND JOHNSON 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; BAYER AG; BAYER PHARMA AG; BAYER HEALTHCARE AG; BAYER CORPORATION; BAYER HEALTHCARE LLC;	:	**JURY TRIAL DEMANDED**

BAYER HEALTHCARE PHARMACEUTICALS INC., Defendants.	:

NOTICE TO PLEAD

NOTICE	ADVISO
You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you. YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER. IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE. Lawyer Referral Service Philadelphia Bar Association 1101 Market Street, 11th Floor Philadelphia, PA 19107 (215) 238-6338	Le han demandado a used en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted. LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL. ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABOGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICOS LEGALES A PERSONAS ELEGIBLES EN

	UN HONORARIO REDUCIDO NINGUN HONORARIO. Lawyer Referral Service Philadelphia Bar Association 1101 Market Street, 11th Floor Philadelphia, PA 19107 (215) 238-6338

CIVIL ACTION COMPLAINT

(2P-Product Liability)

NOW COMES the Plaintiff, [redacted], by and through his undersigned attorneys, JACOBS & CRUMPLAR, P.A. and THE D'ONOFRIO FIRM, LLC, who herein file this Civil Action Complaint and bring this civil action against the above-captioned Defendants based upon the predicate facts, causes of action, and demands for relief set forth in the Counts below. Plaintiff avers the following:

PARTIES

1. Plaintiff, [redacted], at all times relevant hereto, was, and currently is, a resident and citizen of the State of [redacted].

2. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter "Janssen R & D"), is a limited liability company organized, under the laws of New Jersey, with headquarters and a principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Janssen R & D's sole principal or member is Centocor Research Development, Inc., (hereinafter "Centocor") a Pennsylvania corporation with its principal place of business and nerve center located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor is a subsidiary or division of Johnson & Johnson, and has locations involved in the research, design, marketing, sale, and distribution of Xarelto in Horsham, Malvern, Radnor and Ambler, Pennsylvania.

3. Defendant, Janssen R & D, is the holder of the approved New Drug Application ("NDA") for the pharmaceutical prescription drug, Xarelto®, as well as the supplemental NDA for Xarelto.

4. At all times relevant hereto, Janssen R & D was and still is a pharmaceutical company involved in the research, development, sales, marketing and promotion of pharmaceutical products, including Xarelto and rivaroxaban, as set forth herein.

5. At all times relevant hereto, Janssen R & D, and its predecessors-in-interest regularly conducted and continue to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

6. Further, Janssen R & D, maintains significant offices and a place of business in Spring House, Pennsylvania and Exton, Pennsylvania.

7. Defendant, JANSSEN ORTHO, LLC (hereinafter "Janssen Ortho") is a Delaware limited liability company with headquarters and a principal place of business at Bo. Mamey, Carr. 933 Km 0.1, Gurabo, Puerto Rico 00778-9629. Janssen Ortho is a subsidiary of Johnson & Johnson.

8. At all times relevant hereto, Defendant Janssen Ortho manufactured and continues to manufacture Xarelto and had responsibility for the design, manufacture, sale, distribution marketing, promotion, post-marketing surveillance, pharmacovigilance, labeling and detailing of Xarelto. In fact, the Prescribing Information for the Xarelto specifically states, "Finished Product Manufactured by Janssen Ortho, LLC, Gurabo, PR 00778."

9. At all times relevant hereto, Janssen Ortho regularly conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, manufacture, sale,

distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

10. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter "Janssen"), is a corporation organized according to and existing under the laws of the Commonwealth of Pennsylvania, with headquarters and a principal place of business at 420 Delaware Drive, Fort Washington, Pennsylvania, 19034, among other places,.

11. At all times relevant hereto, Janssen was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, promotion, sale, and release for use to the general public of pharmaceuticals, including Xarelto.

12. At all times relevant hereto, Janssen had and continues to have a principal place of business in the Commonwealth of Pennsylvania and regularly conducted and continues to regularly conduct substantial business within Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

13. Defendant, JOHNSON & JOHNSON (hereinafter "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.

14. At all times relevant hereto, Defendant JOHNSON & JOHNSON, had responsibility for the design, development, manufacture, testing, packaging, promotion,

marketing, distribution, labeling, selling, post-market surveillance and/or pharmacovigilance Xarelto.

15. At all times relevant hereto, Johnson & Johnson, regularly conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

16. Defendant, BAYER AG (hereinafter "Bayer AG"), is a German pharmaceutical company with headquarters in Leverkusen, North Rhine-Westphalia, Germany, and is the third largest pharmaceutical company in the world.

17. Defendant, Bayer, AG is the parent/holding company of Defendants, Bayer Corporation, Bayer Healthcare, LLC and Bayer Healthcare Pharmaceuticals, Inc.

18. At all times material hereto, Defendant, Bayer AG, transacted and conducted business in the Commonwealth of Pennsylvania, and has derived substantial revenue and profits from interstate commerce throughout the United States.

19. Defendant, BAYER PHARMA AG, is a German pharmaceutical company. Defendant, Bayer Pharma AG if formerly known as Bayer Shering Pharma AG and is the same corporate entity as Bayer Shering Pharma AG. Bayer Shering Pharma AG is formerly known as Schering AG and is the same corporate entity as Shering AG. Upon information and belief, Shering AG was renamed Bayer Shering Pharma AG and Bayer Shering Pharma AG was subsequently renamed Bayer Pharma AG.

20. Defendant, Bayer Pharma AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

21. Defendant, BAYER HEALTHCARE AG is a German company and is the parent/holding company of Defendants, Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals, Inc. and Bayer Pharma AG. Upon information and belief, at all times relevant hereto, Defendant, Bayer Healthcare AG exercises dominion and control over Defendants, Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals, Inc. and Bayer Pharma AG.

22. Defendant, BAYER CORPORATION (hereinafter "Bayer Corp.") is, and at all times relevant was and remains, an Indiana corporation with its nerve center, headquarters and principal place of business at 100 Bayer Road Pittsburgh, Pennsylvania.

23. Upon information and belief, Defendant, Bayer Corp., is the sole member of Bayer Healthcare, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant, Bayer Pharmaceuticals. Accordingly, Defendant, Bayer Corp., is a parent of Defendant, Bayer Pharmaceuticals.

24. At all times relevant hereto, Bayer Corp., regularly conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

25. Defendant, BAYER HEALTHCARE LLC (hereinafter "Bayer Healthcare") is a Delaware limited liability company with its principal places of business located at 100 Bayer Road, Whippany NJ, 07981.

26. At all times relevant hereto, Bayer Healthcare, regularly conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within

Philadelphia County, which included and continues to include, the research, manufacture, sale, distribution and marketing of Xarelto, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

27. Upon information and belief, Bayer Healthcare's sole member is Defendant, Bayer Corp. which controls from its headquarters in Pittsburgh PA.

28. Bayer Healthcare is a subsidiary of Bayer AG and jointly developed Xarelto with J&J and Janssen R & D.

29. Bayer AG's cooperative partner, J&J and Janssen R & D, submitted the new drug application for Xarelto to the FDA.

30. Defendant, BAYER HEALTHCARE PHARMACEUTICALS INC. ("Bayer Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in 100 Bayer Road, Whippany NJ, 07981.

31. Bayer Pharmaceuticals is the U.S.-based pharmaceuticals operation of Bayer Healthcare, a division of Bayer Corp.

32. Bayer Pharmaceuticals is a subsidiary of Bayer Corp. and jointly developed, marketed and distributed Xarelto with J&J and Janssen R & D. At all times relevant and material hereto, Bayer Pharma was, and still is, a pharmaceutical company involved in the manufacturing, distribution, sale, and release for use to the general public of pharmaceuticals, including Xarelto in Philadelphia County, the Commonwealth of Pennsylvania and throughout the United States.

33. Defendants, Janssen R & D, J&J, Ortho, Janssen, Bayer Corp., Bayer AG, Bayer Healthcare AG, Bayer Pharma AG, Bayer Healthcare, and Bayer Pharmaceuticals shall be referred to herein individually by name or jointly as "Defendants."

34. At all times alleged herein, "Defendants" shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

35. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein.

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

37. At all times relevant and material hereto, Defendants were engaged in the business of researching, developing, designing, licensing, manufacturing, testing, distributing, selling, labeling, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the Commonwealth of Pennsylvania, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the anti-coagulant pharmaceutical Xarelto for the following indications:

a. to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation;

b. to treat deep vein thrombosis ("DVT") and pulmonary embolism ("PE")

c. to reduce the risk of recurrence of DVT and PE; and

d. prophylaxis of DVT in patients undergoing hip and/or knee replacement orthopedic surgical procedures.

JURISDICTION AND VENUE

38. Jurisdiction is proper over the Defendants based on 42 Pa. C.S.A 5301.

39. This Court has proper jurisdiction over Defendant, Janssen, which is a citizen and resident of the Commonwealth of Pennsylvania

40. This Court has personal jurisdiction over the Defendants pursuant to, and consistent with, Pennsylvania's long-arm statute (42 Pa.C.S.§5322) and both the Commonwealth of Pennsylvania's and Federal Constitutional requirements of Due Process in so far that Defendants, acting through agents or apparent agents, committed one or more of the following:

a. Defendants transacted, and continue to transact, business in the Commonwealth of Pennsylvania, 42 Pa.C.S.§5322 (a)(1), and conducted, and regularly conduct business, receive substantial revenues, and sell and perform services in Philadelphia, Philadelphia County, Pennsylvania;

b. Defendants have an interest in, uses, or possess real property in the Commonwealth of Pennsylvania, 42 Pa.C.S.§5322 (a)(5);

c. Requiring Defendants to litigate this claim in the Commonwealth of Pennsylvania does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

41. This action is brought under the common law of the Commonwealth of Pennsylvania and Commonwealth of Pennsylvania Unfair Trade Practices and Consumer Protection Laws to recover damages and other relief, including the costs of suit, and reasonable attorneys' and expert fees, to compensate Plaintiff for injuries sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Xarelto.

42. Venue is proper in this County pursuant to Pa. R.C.P. No. 2179, which provides, in relevant part, that "a personal action against a corporation or similar entity may be brought in and only in (1) the county where its registered office or principal place of business is located;

[or] (2) a county where it regularly conducts business," because all of the Defendants regularly conduct business in Philadelphia County.

43. This is an action for damages, exclusive of interest and costs, which exceeds the sum of fifty thousand dollars ($50,000.00).

NATURE OF THE CASE – GENERAL ALLEGATIONS

44. Xarelto is the trade name for rivaroxaban.

45. Xarelto (rivaroxaban) is an oxazolidinone derivative optimized for inhibiting both free Factor Xa and Factor Xa bound in the prothrombinase complex.

46. Xarelto (rivaroxaban) is a highly selective direct Factor Xa inhibitor with oral bioavailability and rapid onset of action.

47. Inhibition of Factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Xarelto (rivaroxaban) does not inhibit thrombin (activated Factor II).

48. Xarelto is an oral anticoagulant that is available by prescription in oral tablet doses of 20mg, 15mg and 10mg.

49. Defendants, directly or by and through their agents, apparent agents, servants or employees designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed Xarelto as an anti-coagulant primarily used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis ("DVT") and pulmonary embolisms ("PE"), and/or to reduce the risk of recurrence of DVT and or PE and for prophylaxis of DVT for patients undergoing hip and/or knee replacement surgery.

50. The Janssen Defendants applied for an initial New Drug Application (hereinafter "NDA") for Xarelto in July of 2008.

51. Xarelto was approved by the Food and Drug Administration (hereinafter "FDA") on July 1, 2011, to reduce risk of blood clots, DVT, and PE following knee and/or hip replacement surgery. (NDA #022406).

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

53. On November 2, 2012 the FDA approved the expanded clinical use of Xarelto to treat of patients with DVT and PE as well as long-term treatment to prevent recurrence of the same.

54. Defendants launched the Xarelto product in the United States (hereinafter "U.S.") in 2011.

55. The initial 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 "RECORD" studies).

56. The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), and that use of these two treatments was accompanied by similar rates of bleeding.

57. However, the RECORD studies also showed a greater incidence of bleeding, with Xarelto, leading to decreased hemoglobin levels and the need for blood transfusion.[1]

[1] 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

58. The FDA 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 "ROCKET AF" study).

59. The ROCKET AF study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion."[2]

60. 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 (hereinafter collectively referred to as "EINSTEIN" studies).

61. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo.[3]

62. The EINSTEIN-Extension study confirmed that result.[4]

63. The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies

[2] Patel, M.R., et al. *Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation.* N.Engl.J.Med. 2011; 365:883-91

[3] The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism.* N.Engl.J.Med. 2010; 363:2499-510

[4] 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.

also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization.[5]

64. Defendants used the results of the ROCKET AF study, the RECORD studies and the EINSTEIN studies to promote Xarelto in their promotional and marketing materials, including the Xarelto website, which tout the positive results of those studies.

65. However, Defendants' marketing and promotional materials failed to similarly highlight the increased risk set forth in the results of the ROCKET AF, RECORD and EINSTEIN studies of gastrointestinal bleeding and bleeding that required blood transfusions, among other serious bleeding concerns.

66. Defendants zealously marketed and continue to market Xarelto as a new oral anticoagulant treatment alternative to Coumadin (warfarin), which has a long-established history as a safe and effective treatment for preventing stroke, systemic embolism, DVT and PE.

67. Coumadin can be carefully monitored and dose-adjusted by way of regular, routine monitoring of the prothrombin time ("PT") and International Normalization Ratio ("INR"). Additionally, unlike Xarelto, which has no publicly known antidote, the anticoagulation effects of Coumadin are reversible with the administration of vitamin K and/or the administration of coagulation factors such as fresh frozen plasma.

68. Defendants emphasize the purported benefits of treatment with Xarelto over Coumadin, which they refer to as "The Xarelto® Difference," claiming that Xarelto requires "no regular blood monitoring" and has "no known dietary restrictions," thereby allowing Xarelto

[5] The EINSTEIN-PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism.* N.Engl.J.Med. 2012; 366:1287-97.

users to "spend time doing the things [they] enjoy" and "continue to eat the healthy foods [they] like."[6]

69. According to the Defendants' marketing and informational materials, referenced in the paragraphs below, and widely disseminated to the consuming public, "Xarelto® is the first and only once-a day prescription blood thinner for patients with AFib not caused by a heart valve problem, that is proven to reduce the risk of stroke – without routine blood monitoring."[7]

70. As the Defendants state on their website, "XARELTO® has been proven to lower the chance of having a stroke if you have atrial fibrillation (AFib), not caused by a heart valve problem. XARELTO® is an anticoagulant, or blood-thinning medicine that works by helping to keep blood clots from forming."[8]

71. Defendants also claimed that Xarelto "begins working a few hours after you start taking it, and keeps working for as long as take it."[9]

72. Defendants claim that patients with AFib are five times more likely than a person without Afib to suffer from a stroke and that "disability is more likely to be severe" and "the outcome is almost twice as likely to be fatal" and "the chances of having another major stroke go up."[10]

73. Defendants further declare that "XARELTO® is proven to help treat and prevent DVT and PE blood clots" and that Xarelto "reduc[es] the risk of these dangerous clots [from] happening again."[11]

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[6] See http://www.xarelto-us.com/dvt-pe/xarelto-difference

[7] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM357835.pdf

[8] https://www.xarelto-us.com/how-xarelto-works

[9] http://www.xarelto-us.com/how-xarelto-works

[10] http://www.xarelto-us.com/knowing-your-stroke-risk

[11] http://www.xarelto-us.com/dvt-pe/treatment-of-dvt-pe

74. Defendants claim that patients with AFib, DVT, or PE taking Xarelto do not need regular blood monitoring and there are no known dietary restrictions. In addition, patients with AFib only need to take Xarelto once a day with an evening meal.[12]

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

76. In the course of these direct-to-consumer advertisements, the Defendants touted Xarelto as an easy to use, once a day pill with no required monitoring and overstated the efficacy of Xarelto with respect to preventing stroke and systemic pulmonary embolism 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 life-threatening and fatal consequences.

77. In this regard, in the January/February 2013 issue of WebMD magazine, Defendants placed a print advertisement that resulted in the Office of Prescription Drug Promotion (OPDP) of the FDA to send an untitled letter declaring that the Xarelto print advertisement was "false or misleading because it minimizes the risks associated with Xarelto® and makes a misleading claim." Furthermore, the advertisement states "there are no dosage adjustments" in conflict with the product labeling approved by the FDA.[13]

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[12] http://www.xarelto-us.com/dvt-pe/xarelto-difference# and http://www.xarelto-us.com/howxarelto-is-different and http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM357835.pdf

[13] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM357833.pdf , June 6, 2013 FDA Untitled Warning Letter

78. Defendants routinely and aggressively marketed Xarelto as a "one size fits all" drug and in their intense marketing of Xarelto, Defendants misinformed patients and their healthcare providers as to the necessity to routinely monitor any patient requiring a blood thinning agent.

79. The Defendants' marketing materials suggest that Xarelto represents a therapeutic simplification and therapeutic progress of anticoagulation therapy because it does not require dosage adjustments, does not requires patients to undergo periodic monitoring with blood tests and because there were no dietary restrictions.

80. In essence, the Defendants created a new drug, Xarelto, which is not better than warfarin from a safety perspective, and marketed it as a once a day pill that required no routine monitoring. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendants, but ignores patient safety.

81. 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."[14]

82. These "peaks" expose Xarelto users to unreasonable risks for spontaneous bleeding for which there is no antidote or reversal agent.

83. Further, the ISMP noted that the primary reported adverse event related to Xarelto use "was not the well understood risk of hemorrhage. Instead, the largest identifiable category

[14] http://www.ismp.org/QuarterWatch/pdfs/2012Q1.pdf at 22

was serious blood-clot related injury—most frequently pulmonary embolism—the very events rivaroxaban is intended to prevent."[15]

84. Importantly, the ISMP noted that:

> A clinical trial with 14,000 patients had shown that rivaroxaban was no worse than warfarin. [40] But reviewers noted that warfarin had not been optimally used. If rivaroxaban were really inferior to optimally used warfarin—but this was not proven, only suspected—its use could lead to increased death and injury. [41] Reviewers also questioned the convenient once-a-day dosing scheme, saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing. … As with other anticoagulants, the rate of clinically relevant bleeding in clinical studies was high—15% per year of treatment.[16]

In other words, the insufficient testing conducted and the deadly consequences of Xarelto did not go unnoticed.

85. Even more significantly, in the first quarter of 2012, The ISMP "identified 356 reports of serious, disabling, or fatal injury in which rivaroxaban was the primary suspect drug. The report more than doubled from the previous quarter total of 128 cases."[17] However, when the findings were discussed with Defendants, "the company told us that it had reviewed the same data and saw no signal of a safety issue that needed to be addressed."[18]

86. FDA clinical reviewers have stated that "rivaroxaban should not be approved unless the manufacturer conducts further studies to support the efficacy and safety of rivaroxaban" and the FDA website notes that "[a]dverse event reports of thrombocytopenia and venous thromboembolic events were identified" in relationship to Xarelto.[19] However, this information was not portrayed in the warning section on the warning label.

[15] http://www.ismp.org/QuarterWatch/pdfs/2012Q1.pdf at 22.
[16] http://www.ismp.org/QuarterWatch/pdfs/2012Q1.pdf at 22
[17] http://www.ismp.org/QuarterWatch/pdfs/2012Q1.pdf at 22
[18] http://www.ismp.org/QuarterWatch/pdfs/2012Q1.pdf at 24
[19] http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm204091.htm

87. The lack of efficacy of the medication for patients taking Xarelto after hip and knee surgery was not disclosed, resulting in patients ingesting Xarelto and physicians prescribing Xarelto without sufficient information to make an accurate decision concerning the use of this product.

88. Importantly, as stated herein, unlike Coumadin, there is no antidote or reversal agent for Xarelto, so in the event of bleeding complications from Xarelto use, there is no available reversal agent to counteract the anticoagulant effect of Xarelto.

89. Due to the defective nature of Xarelto, persons who were prescribed and ingested Xarelto, for even a brief period of time, including Plaintiff, were at increased risk for developing life-threatening bleeds.

90. Due to the flawed formulation of Xarelto, which according to Defendants does not require regular blood monitoring or frequent doctor follow-up, raises concerns about the risk of stroke, bleeding, and blood clots if not taken properly or absorbed properly, particularly in patients with poor renal function.

91. In addition, "[p]rominent U.S. [cardiologists and health care professionals] stress that neither new drug [Xarelto] has a known antidote for a bleeding emergency, as warfarin does."[20]

92. Defendants' pharmaceutical Xarelto led to 968 suspected undesirable side-effects including 72 cases of death in Germany in just the first eight months of 2013.[21]

[20] Ransdell Pierson. "Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners" Huffpost Healthy Living. 14th June 2012

[21] Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" http://www.reuters.com/article/2013/09/08/us-bayer-xareltoidUSBRE9870AH20130908

93. Defendants fervently marketed Xarelto using print advertisements, online marketing on their website, and video advertisements with no regard to the accuracy and repercussions of their misleading advertising in favor of increasing sales.

94. Defendants placed more value into ensuring that their profits would continue instead of working on minimizing the serious, disabling, or fatal injuries that were occurring due to the drug they were marketing and promoting.

95. Indeed, their marketing efforts were successful, as Defendants boast that Xarelto has "been prescribed to more than ten million people around the world to help treat or reduce their risk of dangerous clots." According to Defendants' Xarelto website, Xarelto "is the most prescribed blood thinner in its class in the US."[22]

96. As a result of Defendants' intense marketing, "[a]bout 130,000 U.S. prescriptions were written for Xarelto® in the first three months of 2012" resulting in large profits as Xarelto costs approximately $3,000 a year versus $200 for generic warfarin.[23]

97. Similarly, as a result of Defendant's extreme marketing tactics within the United Kingdom, Defendants also made 219 million Euros in sales from Xarelto, more than three times as much as during the same period last year.[24]

98. Defendants concealed their knowledge that Xarelto can cause life threatening, irreversible bleeds from Plaintiff, other consumers, the general public, and the medical community including Plaintiff's prescribing physicians.

[22] https://www.xarelto-us.com/how-xarelto-works
[23] Ransdell Pierson. "Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners" Huffpost Healthy Living. 14th June 2012
[24] Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" http://www.reuters.com/article/2013/09/08/us-bayer-xareltoidUSBRE9870AH20130908

99. Indeed, the Defendants did not properly warn of the irreversible nature of Xarelto in the "Warnings and Precautions" section of the products warning label. The only warnings provided by Defendants were as follows:

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events After Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Risk of Bleeding:** XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO® in patients with active pathological hemorrhage.
  - A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable.
  - Concomitant use of other drugs affecting hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, and NSAIDs.
- **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. To reduce the potential risk of bleeding associated with the concurrent use of rivaroxaban and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of rivaroxaban. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of rivaroxaban is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An epidural catheter should not be removed earlier than 18 hours after the last administration of XARELTO®. The next XARELTO® dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of XARELTO® is to be delayed for 24 hours. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.
- **Use in Patients With Renal Impairment:**
  - **Nonvalvular Atrial Fibrillation:** Avoid the use of XARELTO® in patients with creatinine clearance (CrCl) <15 mL/min, since drug exposure is increased. Discontinue XARELTO® in patients who develop acute renal failure while on XARELTO®.
  - **Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.
  - **Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.
- **Use in Patients With Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- **Use With P-gp and Strong CYP3A4 Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with combined P-gp and strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, lopinavir/ritonavir, ritonavir, indinavir/ritonavir, and conivaptan). Avoid concomitant use of XARELTO® with drugs that are P-gp and strong CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin, St. John's wort).
- **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing and is not readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).
- **Patients With Prosthetic Heart Valves:** The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.
- **Acute PE in Hemodynamically Unstable Patients/Patients Who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

100. Specifically, Defendants did not adequately inform Plaintiff, other consumers, the general public, and the medical community including Plaintiff's prescribing physicians,

about the risks of uncontrollable bleeds associated with Xarelto usage, nor did Defendants warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur.

101. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but rather merely mentioned this extremely important fact in the overdosage section.

102. As seen in the "Full Prescribing Information" provided by Defendants, Defendants reveal that they did not test for all the possible reversal agents for this dangerous drug since "[a] specific antidote for rivaroxaban is not available" and "[u]se of procoagulant reversal agents such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate (APCC), or recombinant factorVlla (rFVllA) may be considered but has not been evaluated in clinical trials." However, this is buried in small print.

103. Even in the "Warnings and Precautions" section of the August 2013 Highlights of Prescribing Information, the irreversible nature of the medication Xarelto was not revealed to patients or their prescribing doctors.

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS, and (B) SPINAL/EPIDURAL HEMATOMA

See full prescribing information for complete boxed warning

PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any anticoagulant, including XARELTO, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy (2.2, 2.6, 5.1, 14.1).

SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas have occurred in patients treated with XARELTO who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis (5.2, 5.3, 6.2).

Monitor patients frequently for signs and symptoms of neurological impairment and if observed, treat urgently. Consider the benefits and risks before neuraxial intervention in patients who are or who need to be anticoagulated (5.3).

104. Defendants merely indicated that there was a risk for bleeding and side-stepped the important issue of reversing the effects of Xarelto should a bleed occur as seen below:

----------WARNINGS AND PRECAUTIONS----------

- Risk of bleeding: XARELTO can cause serious and fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.2)
- Pregnancy related hemorrhage: Use XARELTO with caution in pregnant women due to the potential for obstetric hemorrhage and/or emergent delivery. Promptly evaluate signs and symptoms of blood loss. (5.7)
- Prosthetic heart valves: XARELTO use not recommended (5.8)

105. Defendants' boxed warning did not address the increased risk for serious and fatal bleeding, despite the fact that the information listed on their website originating from the Rocket AF clinical trial sponsored by Defendants state that in comparison to warfarin, patients taking Xarelto have more gastrointestinal bleeds and need more transfusions. In spite of this reference regarding bleeds, the information is still wholly inadequate because this information was not conveyed in the boxed warning on the Xarelto label.[25]

106. Importantly, Xarelto still does not have a "Black Box" warning informing patients or prescribing doctors that Xarelto can cause irreversible and uncontrollable bleeds.

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including XARELTO®, increases the risk of thrombotic events. If anticoagulation with XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas have occurred in patients treated with XARELTO® who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- Use of indwelling epidural catheters
- Concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, see Drug Interactions
- A history of traumatic or repeated epidural or spinal punctures
- A history of spinal deformity or spinal surgery
- Optimal timing between the administration of XARELTO® and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

[25] http://www.xareltohcp.com/reducing-stroke-risk/safety.html

107. In fact, a label change as recent as March of 2014 fails to contain a Black Box Warning regarding irreversible bleeding episodes.

108. In addition to its failure to adequately and appropriately update its warning labels for the Xarelto product, Defendants have failed to issue a "Dear Doctor" letter that sufficiently outlines the dangers of prescribing and administering Xarelto to a patient.

109. The current warning is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including Plaintiff.

110. Even if the warnings were sufficient, which Plaintiff strongly denies, Xarelto still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug.

111. Xarelto is quite simply dangerous and defective as formulated and the Defendants should withdraw Xarelto from the market.

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

113. Upon information and belief, prior to Plaintiff's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

114. 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.

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

116. 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.

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

118. 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."

119. 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.

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

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

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

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

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

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

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

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

f. failed to advise prescribing physicians, such as the Plaintiffs physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;

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

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

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

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

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

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

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

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

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

123. 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 herein.

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

125. 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.

126. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

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

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

129. At all times relevant hereto, when warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

130. At all times relevant hereto, Defendants concealed their knowledge of Xarelto's defects from Plaintiff, the FDA, the public in general, and/or the medical community specifically. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in

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

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

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

FACTUAL ALLEGATIONS SPECIFIC TO PLAINTIFF

133. Upon information and belief, Plaintiff, [redacted] was prescribed Xarelto in a 20mg dose in [redacted] 2014, by his physician [redacted] for treatment of non-valvular atrial fibrillation.

134. Upon information and belief, Plaintiff ingested the prescription medication Xarelto as directed by his physicians.

135. [redacted].

136. Plaintiff, [redacted], was hospitalized [redacted] and was diagnosed with a gastrointestinal bleed and given blood transfusions.

137. As a direct result of being prescribed Xarelto for this period of time, Plaintiff suffered significant injuries, such as those described above.

138. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to Plaintiff's ingestion of Xarelto. Plaintiff accordingly seeks damages associated with these injuries.

139. Plaintiff would not have used Xarelto had Defendants properly disclosed the risks associated with its use, as safer alternatives were available.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATION

140. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

141. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

142. Defendants, through failing to disclose, for three years, the truth about the safety and efficacy of Xarelto, to Plaintiff's physicians and/or Plaintiff, and by misrepresenting Xarelto as safe and efficacious for its intended use, actively concealed from said individuals the true risks associated with the use of Xarelto drug products.

143. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein.

144. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action.

145. Neither Plaintiff nor Plaintiff's physicians, could have possibly determined the nature, extent and identity of related health risks associated with Xarelto.

146. Plaintiff and Plaintiff's physicians reasonably relied on Defendants to disseminate truthful and accurate safety and efficacy information about its drug and warn of the side effects complained of herein.

147. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of Xarelto.

148. Defendants, at all times relevant hereto, were under a duty to disclose the true character, quality, and nature of Xarelto because this was non-public information over which the Defendants had and continue to have, exclusive control, and because Defendants knew this information was not available to the Plaintiff, the Plaintiff or Plaintiff's physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate Plaintiff for her injuries.

COUNT I. STRICT PRODUCTS LIABILITY

149. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

150. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, pharmaceuticals, including Xarelto, for the sale to, and use by, members of the general public and specifically to Plaintiff.

151. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants reached Plaintiff without substantial change and was ingested as directed.

152. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was in an unreasonably and inherently dangerous, defective and unsafe condition, which was dangerous to others when it entered into the stream of commerce and was used by Plaintiff.

153. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, 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, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

154. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, 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.

155. At all times relevant hereto, the Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by Defendants was, and still is, defective, unsafe and inherently dangerous and Defendants knew or should have known that Xarelto was, and still is, defective, unsafe and inherently dangerous, especially when used in the form and manner provided, directed, marketed and advertised by the Defendants.

156. Defendants, as manufacturers and distributors of pharmaceutical drugs, including Xarelto, are held to the level of knowledge of an expert in the field, and further, Defendants

knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Xarelto were inadequate.

157. Defendants had and continue to have a duty to design and manufacture a product that was not unreasonable dangerous for its normal, usual and intended use.

158. Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed an unreasonably dangerous and defective prescription drug, Xarelto, which created an unreasonable risk to the health of consumers and to the Plaintiff, specifically; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

159. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by the Defendants reached their intended users in the same defective and unreasonably dangerous condition in which it was manufactured.

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

161. Defendants had and continue to have a duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Xarelto, as it became or could have become available to Defendants.

162. Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed an unreasonably dangerous and defective prescription drug, Xarelto, to health care providers empowered to prescribe and dispense Xarelto to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data.

163. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Xarelto, which resulted in injury to Plaintiff.

164. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonable and dangerous side effects, they continued to promote, market, label, advertise, distribute and sell Xarelto without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Xarelto.

165. The Xarelto designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed by the Defendants was defective due to inadequate post-market surveillance and/or warnings because after Defendants knew or should have known of the risks of serious side effects, the failed to provide adequate warnings to users and/or consumers of the product and continued to promote, market, advertise, distribute and sell Xarelto.

166. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury or death as a result of Defendants' failures.

167. Defendants' defective design, manufacture, research, testing, advertising, promoting, marketing, labeling, sale, and distribution of Xarelto, as set forth herein, was done willfully, intentionally and with reckless disregard to the life and safety of Plaintiff and the general public.

168. Based on the foregoing, the Defendants are strictly liable to the Plaintiff for the design, manufacture, research, testing, advertising, promoting, marketing, labeling, sale, and distribution of a defective product, Xarelto.

169. The foregoing defects in the drug Xarelto were a substantial factor in causing Plaintiff's injuries.

170. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

171. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

172. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

173. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT II. BREACH OF WARRANTY - BREACH OF EXPRESS WARRANTY

174. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

175. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Xarelto.

176. Defendants expressly warranted that Xarelto was safe and effective to Plaintiff and to other members of the general and consuming public.

177. Defendants marketed, promoted, sold, distributed and/or otherwise released into the stream of commerce, Xarelto as a safe and effective product.

178. Defendants expressly represented to Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, 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 accurately tested and fit for its intended use.

179. Xarelto does not conform to those representations made by Defendants because it is not safe and has numerous serious side effects, including life-threatening and irreversible bleeding events.

180. The Defendants and their agents, servants and/or employees, breached their express warranty by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Designing, manufacturing, advertising, promoting, marketing, labeling, selling, distributing and otherwise placing into the stream of commerce, Xarelto in an defective and unreasonably dangerous condition;

b. Failing to warn and/or place accurate and adequate warnings and instructions on Xarelto;

c. Failing to adequately test Xarelto;

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

181. Members of the medical community, including Plaintiff's prescribing physicians, relied upon the representations and warranties of the Defendants for use of Xarelto in recommending, prescribing and/or dispensing Xarelto to their patients, including the Plaintiff.

182. Plaintiff, and other members of the general and consuming public were the intended third-party beneficiaries of the warranty.

183. Plaintiff relied on the representations and warranties of the Defendants that Xarelto was safe and effective when he took the medication.

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

185. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

186. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

187. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

188. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or

common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT III. BREACH OF WARRANTY – BREACH OF IMPLIED WARRANTIES

189. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

190. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Xarelto.

191. At all times that Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Xarelto, they knew of its intended uses to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reduce the risk of recurrence of DVT and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

192. Defendants impliedly represented and warranted Xarelto to Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, that Xarelto was safe and of merchantable quality and was fit for use for the ordinary purposes for which the product was to be used, as set forth above.

193. Xarelto does not conform to those representations and warranties made by Defendants because it is not safe, not of merchantable quality, not fit for its intended uses, and has numerous serious side effects, including life-threatening and irreversible bleeding events.

194. Defendants' implied representations and warranties were false, misleading, and inaccurate because Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, not fit for its intended uses and defective.

195. Members of the medical community, including Plaintiff's prescribing physicians, relied upon the implied representations and warranties of the Defendants for use of Xarelto in recommending, prescribing and/or dispensing Xarelto to their patients, including the Plaintiff.

196. Plaintiff, and other members of the general and consuming public were the intended third-party beneficiaries of the warranty.

197. Plaintiff relied on the representations and warranties of the Defendants that Xarelto was safe and effective for treatment of non-valvular atrial fibrillation when he took the medication.

198. Defendants' breach of their implied warranties of merchantability and fitness for a particular purpose were the direct and proximate result of the Plaintiff's injuries.

199. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

200. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

201. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

202. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT IV. NEGLIGENCE

203. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

204. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care in the design, manufacture, research, testing, advertising, promoting, marketing, sale, and distribution of their prescription medications, including the Xarelto into the stream of commerce.

205. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care in the design, manufacture, research, testing, advertising, promoting, marketing, labeling, sale, and distribution of their prescription medications, including the Xarelto to make sure that the product would not cause unreasonable, dangerous side effects.

206. Defendants failed to exercise reasonable care in the design of Xarelto because as designed, manufactured, marketed, labeled, sold and distributed, Xarelto was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

207. Defendants also failed to exercise reasonable care in the marketing of Xarelto because they failed to warn, that as designed, manufactured, marketed, labeled, sold and distributed, Xarelto was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

208. The Defendants and their agents, servants and/or employees, breached their duty of care and were negligent by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Failing to use due care in developing, testing, designing, and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was being used for treatment;

b. Designing, manufacturing, advertising, promoting, marketing, labeling, selling, and distributing Xarelto without properly, adequately and thoroughly testing the drug to determine whether it was safe for use;

c. Failing to adequately and accurately warn the Plaintiff, Plaintiff's physicians, the general public, the medical profession at large and the FDA of the dangers of Xarelto;

d. Failing to accompany their product with proper or adequate warnings, or labeling regarding adverse side effects and health risks associated with the use of Xarelto and the comparative severity and duration of such adverse effects;

e. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

f. Failing to accompany their products with proper, accurate or adequate rate of incidence or prevalence of irreversible bleeds;

g. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

h. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto;

i. Failing to warn Plaintiff, Plaintiff's physicians, the general public, the medical profession at large and the FDA that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

j. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Xarelto and patients taking Xarelto;

k. Failing to adequately test and/or warn about the use of Xarelto, including, without limitations, the possible adverse side effects and health risks caused by the use of Xarelto;

l. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent or antidote;

m. Designing, manufacturing, advertising, promoting, marketing, labeling, selling, and distributing Xarelto, a product that could not be used safely due to the lack of a known reversal agent or antidote;

n. Designing, manufacturing, advertising, promoting, marketing, labeling, selling, distributing and placing into the stream of commerce, a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;

o. Failing to remove Xarelto from the market when Defendants knew or should have known of the likelihood of serious side effects and injury to its users;

p. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of bleeds and related dangerous conditions to individuals taking Xarelto; and

q. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use;

r. Concealing and/or misrepresenting information from Plaintiff, Plaintiff's physicians, the general public, the medical profession at large and the FDA about the severity or risks and dangers of Xarelto when they knew or should of known that Xarelto was unsafe and dangerous.

209. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonable dangerous side effects, the Defendants continued and still continue to manufacture, market, promote, advertise, sell and distribute Xarelto to consumers, including the Plaintiff.

210. Defendants knew or should have known that consumers, including the Plaintiff, would foreseeably suffer injure as a result of the Defendants' failure to exercise reasonable case, as set forth above.

211. The Xarelto that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was in when it left the control of Defendants.

212. Xarelto's ability to cause serious personal injuries and damages, such as those suffered by Plaintiff, was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Xarelto as directed and without change in its form or substance.

213. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto was the proximate cause of Plaintiff's injuries, harm, economic loss and damages.

214. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

215. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

216. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

217. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or

common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT V. NEGLIGENCE – FAILURE TO WARN

218. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

219. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care to warn of the dangerous conditions and/or of the facts that made Xarelto likely to be dangerous.

220. Defendants owed a continuing duty to warn Plaintiff, prescribing physicians and the general public, of the dangers associated with Xarelto.

221. At all times relevant hereto, including the time period before Plaintiff ingested Xarelto, and during the time period in which he took Xarelto, Defendants knew or should have known that Xarelto was dangerous and created an unreasonable risk of bodily harm to consumers, including the Plaintiff.

222. The Defendants and their agents, servants and/or employees, breached their duty of care and were negligent by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Failing to provide proper, accurate or adequate warnings or labeling regarding all possible adverse side effects and health risks associated with the use of Xarelto;

b. Failing to provide proper, accurate or adequate warnings or labeling regarding the comparative severity and duration of the adverse side effects and health risks associated with the use of Xarelto;

c. Failing to provide proper, accurate or adequate rate of incidence or prevalence of irreversible bleeds;

d. Failing to accompany their product with all proper, accurate or adequate warnings or labeling regarding all possible adverse side effects, health risks and/or rate of incidence or prevalence of irreversible bleeds associated with the use of Xarelto and the comparative severity and duration of same;

e. Failing to provide proper, accurate or 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;

f. Failing to provide proper, accurate or 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;

g. Failing to provide proper, accurate or adequate warnings regarding the potential for dangerous peaks and troughs associated with a once-a-day pill which could expose patients to acute bleeding events;

h. Failing to provide proper, accurate or adequate warnings to the Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, that Xarelto's risk of harm was unreasonable and that there were safer and more effective alternative medications available to Plaintiff and other consumers;

i. Failing to provide proper, accurate or adequate warnings to the Plaintiff, Plaintiff's physicians, the general public and the medical profession at large, about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially serious and/or fatal dangerous side effects associated with the use of Xarelto.

223. Xarelto was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks and reactions associated with Xarelto, including but not limited to the prevalence of irreversible bleeding, and other serious injuries and side effects despite

Defendants' knowledge of the increased risk of these injuries over other anticoagulation therapies available.

224. Xarelto was defective due to inadequate post-marketing warnings and instruction because Defendants knew or should have known of the risk and danger of serious bodily harm and or death from the use of Xarelto but failed to provide an adequate warning to patients and prescribing physicians of the product, knowing the product could cause serious injury and or death.

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

226. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians of the risk of irreversible bleeding and other serious injuries and side effects, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk, as set forth herein.

227. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

228. Plaintiff was prescribed and used Xarelto for its intended purpose.

229. Plaintiff consumed the Xarelto as directed and without change in its form or substance.

230. Plaintiff could not have known about the dangers and hazards presented by Xarelto.

231. Had Plaintiff received adequate warnings regarding the risks of Xarelto, he would not have used Xarelto.

232. Likewise, if Plaintiff's prescribing physicians received adequate warnings regarding the risks of Xarelto, Plaintiff's prescribing physicians would not have recommended, prescribed, dispensed, administered and/or relied on the drug, Xarelto.

233. Xarelto's ability to cause serious personal injuries and damages, such as those suffered by Plaintiff, was not due to any voluntary action or contributory negligence of Plaintiff.

234. As a direct and proximate result of Xarelto's defective, inaccurate, inadequate, incomplete and inappropriate warnings, Plaintiff has suffered severe physical injuries, harm, economic loss and damages as described herein.

235. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

236. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

237. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

238. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT VI. NEGLIGENCE – UNREASONABLE MARKETING OF A DANGEROUS DRUG AND UNREASONABLE FAILURE TO REMOVE THE DRUG FROM THE MARKET

239. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

240. Defendants owed a duty to Plaintiff and to the general public, to not introduce a drug into the market, or continue a previous tender of a drug, including the Xarelto at issue in this lawsuit, that was unreasonably dangerous for any person to use it and was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

241. The Defendants and their agents, servants and/or employees, breached their duty of care and were negligent by, but not limited to, the following acts, misrepresentations, and/or omissions:

a. Failing to exercise reasonable and ordinary care in that the drug Xarelto was so unreasonably dangerous and defective in design that it never should have been on the market or taken by anyone;

b. Failing to exercise reasonable and ordinary care in the design, research, development, manufacture, sale, testing, promotion, marketing, labeling and or distribution of the drug Xarelto;

c. Tendering into the market a drug which Defendants knew or should have known was so dangerous that it should not have been taken by anyone;

d. Violating its duty of care in design by tendering into the market a drug which it knew or should have known should not have been taken by anyone;

e. Violating its duty of care in design in marketing by tendering into the market a drug which it knew or should have known should not have been taken by anyone;

f. Violating its duty of care in design by placing an unsuitable product into the market for public consumption;

g. Misrepresenting that no monitoring was necessary while Plaintiff was taking Xarelto.

242. The Xarelto that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was in when it left the control of Defendants.

243. Xarelto's ability to cause serious personal injuries and damages, such as those suffered by Plaintiff, was not due to any voluntary action or contributory negligence of Plaintiff.

244. Plaintiff consumed the Xarelto as directed and without change in its form or substance.

245. Defendants' violation of its duty of care resulted in an untenably dangerous product being placed into the marketplace which was the direct and proximate cause of Plaintiff's injuries, harm, economic loss and damages.

246. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

247. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

248. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

249. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be

determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT VII. NEGLIGENT MISREPRESENTATION

250. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

251. Defendants had a duty to provide Plaintiff, Plaintiff's physicians, the consuming public and the medical profession at large with true, honest and accurate information and warnings of any and all known risks and side of Xarelto, which they designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed.

252. At all times relevant hereto, Defendants misrepresented that Xarelto was a safe and effective anticoagulant medication.

253. At all times relevant hereto, Defendants misrepresented that Xarelto had been tested and was found to be safe and effective in 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.

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

255. Defendants' representations, as set forth herein, were, in fact, false.

256. Defendants knew or should have known that their representations regarding Xarelto were false and that they had a duty to disclose the dangers of Xarelto.

257. Defendants failed to exercise reasonable care in their representations concerning Xarelto while they designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, and distributed Xarelto because they negligently misrepresented Xarelto's high risk of unreasonable, dangerous and serious side effects.

258. Defendants failed to disclose material facts and made the misrepresentations with the intent to induce Plaintiff, Plaintiff's physicians, the consuming public and the medical profession at large, to act in reliance by using, recommending or prescribing Xarelto.

259. Defendants breached their duty to provide Plaintiff, Plaintiff's physicians, the consuming public and the medical profession at large with true, honest and accurate information and warnings of any and all known risks and side of Xarelto.

260. Plaintiff justifiably relied on Defendants' representations, misrepresentations, omissions and failures to disclose material facts.

261. Defendants' negligent misrepresentations, omissions and failures to disclose material facts were the direct and proximate cause of Plaintiff's injuries.

262. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

263. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

264. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

265. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT VIII. FRAUD AND CONSPIRACY

266. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

267. At all times relevant hereto, Defendants designed, manufactured, researched, tested, advertised, promoted, marketed, labeled, sold, distributed and otherwise placed into the stream of commerce, the prescription drug, Xarelto.

268. Defendants, having undertaken the design, manufacture, research, testing, advertisement, promotion, marketing, labeling, sale, and distribution of Xarelto described herein, owed a duty to provide accurate, honest and complete information regarding these products.

269. Defendants knew or should have known, that Xarelto was unreasonably dangerous and defective, and caused serious, and often fatal, irreversible bleeds.

270. Despite their knowledge, Defendants fraudulently suppressed and concealed material information regarding the safety and efficacy of Xarelto, including information regarding the risk of life-threatening bleeding events.

271. Further, as a result of Defendants' research, testing and/or lack thereof, as set forth more fully above, Defendants blatantly and intentionally distributed false information including, but not limited to, assuring Plaintiff, Plaintiff's physicians, the consuming public, the medical profession at large, and the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reduce the risk of recurrence of DVT and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

272. As a result of Defendants' research, testing and/or lack thereof, as set forth more fully above, Defendants intentionally omitted certain results of testing and research in their disclosures to Plaintiff, Plaintiff's physicians, the consuming public, the medical profession at large, and the FDA.

273. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results that were not favorable to the Defendants and results that demonstrated that Xarelto was not a safe means of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reduce the risk of recurrence of DVT and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

274. At all times relevant hereto, while Defendants concealed the fact that Xarelto was not safe, they were under a duty to communicate and disclose such information to Plaintiff,

Plaintiff's physicians, the consuming public, the medical profession at large, and the FDA in such a manner that they could appreciate the risks associated with Xarelto.

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

276. At all times relevant hereto, Defendants submitted documents to the FDA, as well as Plaintiff, Plaintiff's physicians, the consuming public, and the medical profession at large, which contained false claims and false representations that Xarelto did not present serious health and/or safety risks.

277. At all times relevant hereto, Defendants submitted documents to the FDA, as well as Plaintiff, Plaintiff's physicians, the consuming public, and the medical profession at large, which contained false claims and false representations that Xarelto did not present serious health and/or safety risks greater than other forms of oral anticoagulants.

278. Defendants had a duty when disseminating information to the public, to disseminate truthful information and a duty to not deceive the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large, and the FDA.

279. Defendants distributed and disseminated information to the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA including, but not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, website advertisements, magazine advertisements, billboards, and other commercial and social media, which contained material representations of fact and/or omissions of material facts.

280. Defendants distributed and disseminated information to the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA in

which Defendants intentionally included representations that Xarelto carried the same risks, hazards and/or dangers as other forms of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reduce the risk of recurrence of DVT and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

281. The information that Defendants distributed and disseminated information to the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA, were all false and misleading.

282. Plaintiff and his prescribing physicians relied upon the Defendants' false and outrageous representations regarding the safety and efficacy of Xarelto.

283. The Defendants' representations and claims regarding Xarelto, including, but not limited to, those set forth above, were false when made and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

284. The Defendants' false representations and false claims regarding Xarelto, including, but not limited to, those set forth above, were made with the intention of deceiving and defrauding the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA, and were made in order to induce Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA, to rely on the false representations and false claims and caused Plaintiff and Plaintiff's physicians to purchase, use, request, dispense, prescribe, recommend and/or to continue to use Xarelto.

285. The Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to Plaintiff, Plaintiff's physicians, the general

and consuming public, the medical profession at large and the FDA, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternative medications.

286. The Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto.

287. Upon information and belief, Defendants fraudulently suppressed and concealed safety issues associated with the use of Xarelto in order to induce physicians to recommend its use to patients, including Plaintiff.

288. Upon information and belief, Defendants fraudulently suppressed and concealed material information regarding the safety and efficacy of Xarelto, including information regarding the risk of life-threatening bleeding events, intentionally and in an effort to maintain and support the sales volume of Xarelto.

289. Upon information and belief, Defendants made the false claims and representations described herein with the intent to deceive and defraud the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA; to gain the confidence of the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA; to falsely ensure the quality and fitness for use of Xarelto and to induce Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large and the FDA, to purchase, request, dispense, prescribe, recommend and/or to continue to use Xarelto.

290. Defendants used direct-to-consumer marketing and advertising to market, promote, advertise, sell and/or distribute Xarelto.

291. Defendants' practices relating to their promotion of Xarelto created and/or reinforced a false impression as to its safety.

292. Defendants' practice of promoting Xarelto placed and continues to place all consumers of Xarelto at risk for serious injury resulting from its potentially lethal side effects.

293. Plaintiff and/or Plaintiff's physicians did, in fact, rely on and believe the Defendants' representations and claims regarding Xarelto, including, but not limited to, those set forth above, to be true at the time they were made and relied upon those representations as well as the superior knowledge of the Defendants and were thereby induced to purchase, request, rely on, dispense, prescribe, recommend and/or to continue to use on the drug, Xarelto.

294. Plaintiff purchased and used Xarelto for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices.

295. Plaintiff and Plaintiff's physicians did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

296. Plaintiff did not discover the true facts with regard to the dangerous and serious health and/or safety concerns of Xarelto and the false representations and false claims of the Defendants, nor could Plaintiff have discovered the true facts with reasonable diligence.

297. If Plaintiff knew the true facts with regard to the dangerous and serious health and/or safety concerns of Xarelto, Plaintiff would not have purchased, used and/or relied on the drug, Xarelto.

298. Likewise, if Plaintiff's prescribing physicians knew the true facts with regard to the dangerous and serious health and/or safety concerns of Xarelto, Plaintiff's prescribing

physicians would not have recommended, prescribed, dispensed, administered and/or relied on the drug, Xarelto.

299. Defendants agreed and conspired with the Defendants named herein to suppress and misrepresent the risks, dangers and hazards associated with Xarelto use.

300. Defendants engaged in investigations and research as to the risks, dangers and hazards associated with Xarelto use and often edited out material deemed to be potentially harmful to the pharmaceutical industry and only published favorable portions of their findings and/or refrained from publishing anything.

301. The Defendants knowingly and willfully conspired among themselves to perpetuate the actions and omissions referred to herein as well as aided and abetted their co-defendants and manufacturers of Xarelto products in keeping the Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large ignorant of the risks, dangers and hazards associated with Xarelto use knowing that they would not discover or realize the danger or would fail to protect themselves against it.

302. Defendants had reason to expect that as a result of such representation, Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large would use, purchase, recommend, prescribe and/or dispense Xarelto.

303. Even after the risks, dangers and hazards associated with Xarelto use finally began to be known to Plaintiff, Plaintiff's physicians, the general and consuming public, the medical profession at large, Defendants continued to act wrongfully both individually and together in a conspiracy to mislead and misrepresent the extent of the past wrongful actions and omissions and to destroy records and hide witnesses and other evidence and to such other wrongful and unnecessary action so as to: Prevent and delay Plaintiff and others similarly

situated from filing legal action to recover for these injuries and/or; Defeat and/or delay such legal actions and the final collection of any judgment.

304. Similarly, Defendants aided and abetted each other and the manufacturers, suppliers, and distributors of Xarelto in keeping the true risks, dangers and hazards associated with Xarelto use secret and/or misrepresented.

305. Defendants' foregoing acts of fraud and/or conspiracy are the direct and proximate cause of Plaintiff's injuries.

306. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

307. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

308. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

309. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT IX. VIOLATION OF CONSUMER PROTECTION LAWS

311. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g) and further alleges as follows:

312. Defendants have a statutory duty to refrain from making false or fraudulent representations in the sale and promotion of pharmaceuticals, including Xarelto pursuant to various Consumer Protection Laws.

313. Defendants have a statutory duty to refrain from engaging in deceptive acts or practices in the sale and promotion of pharmaceuticals, including Xarelto pursuant to various Consumer Protection Laws.

314. Defendants' conduct constituted unfair and deceptive acts or practices, including, but not limited to the following:

a. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b. Publishing instructions and product material containing inaccurate and incomplete factual information;

c. Misrepresenting the nature, quality, and characteristics about the product;

d. Advertising goods or services with the intent not to sell them as advertised; and

e. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

315. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Xarelto, which induced Plaintiff to purchase and use Xarelto.

316. 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 regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.

317. Defendants mischaracterized the true nature, quality and characteristics of Xarelto, in marketing, promoting and advertising it as a once a day pill with no routine blood monitoring or dosage adjustment requirements.

318. 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.

319. Defendants' conduct, as described above, was a material cause of Plaintiff's decision to purchase and use Xarelto.

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

321. Defendants' violation of Consumer Protection Laws, as set forth above, was the direct and proximate cause of Plaintiff's injuries.

322. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

323. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

324. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

325. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

COUNT X. DAMAGES- COMPENSATORY AND PUNITIVE

326. Plaintiff incorporates by reference each and every paragraph of this Complaint, as if the same were set forth herein at length, as expressly permitted by Pa.R.C.P. 1019(g), and further alleges as follows:

327. Plaintiffs are entitled to both compensatory and punitive damages.

328. Defendants mislead both the medical community and the public at large, including Plaintiff and Plaintiff's physicians, by making false representation about and concealing pertinent information regarding Xarelto.

329. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Xarelto despite information demonstration the product was unreasonably dangerous.

330. As a proximate result of Defendants' negligent and reckless acts and omissions, Plaintiff suffered gastrointestinal bleeding requiring blood transfusion resulting from his ingestion of Xarelto.

331. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

332. Plaintiffs have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured.

333. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

334. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendants.

335. The facts averred herein, and all reasonable inferences which can be drawn from those facts, demonstrate conduct so outrageous as to rise to the level of intentional, willful, wanton and/or reckless conduct.

336. The facts averred herein, and all reasonable inferences which can be drawn from those facts, demonstrate reckless indifference to the rights, health, safety and welfare of others, including the Plaintiff.

337. The facts averred herein, and all reasonable inferences which can be drawn from those facts, demonstrate that the Defendants knew or had reason to know of facts which created a high risk of physical harm to the public at large and specifically to the Plaintiff.

338. The facts averred herein, and all reasonable inferences which can be drawn from those facts, demonstrate that the Defendants proceeded to act in conscious disregard of and/or reckless indifference to the known high risk of physical harm to the public at large and specifically to the Plaintiff.

339. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

340. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff was caused to suffer serious and dangerous side effects, including severe and life-threatening bleeding, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain, and mental anguish, diminished enjoyment of life, shortened life expectancy, and expenses for hospitalization.

341. As a direct and proximate result of the actions and omission of the Defendants described herein, Plaintiff suffered and incurred damages, including medical expenses; and other economic and non-economic damages flowing from the injuries of the Plaintiff.

342. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

343. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case as may be determined by choice of law principles regarding or whether arising under statute and/or common law and reserves its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants as follows:

344. For judgment for damages sufficient to compensate for damages, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiff as a result of ingesting Defendants' Xarelto drug product;

345. For compensatory damages according to proof, including lost wages, pain, suffering and mental anguish and any and all damages allowed under applicable law;

346. For punitive damages, in an amount to be awarded as provided by law;

347. For reasonable costs, including attorney's fees as permitted by law; and

348. For all other just and proper relief.

Respectfully submitted,

Dated: [redacted]

By: /s/ Louis F. D'Onofrio

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