

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NANCY PACKARD, Individually and as Personal
Representative of the Estate of WILLIAM N.
PACKARD, JR.

Plaintiffs,

v.

JANSSEN RESEARCH & DEVELOPMENT, LLC
f/k/a JOHNSON AND JOHNSON
PHARMACEUTICALS RESEARCH AND
DEVELOPMENT LLC; JOHNSON & JOHNSON
COMPANY; JANSSEN ORTHO, LLC; JANSSEN
PHARMACEUTICALS, INC., f/k/a ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
BAYER CORPORATION; BAYER AG; BAYER
HEALTHCARE LLC; and BAYER
HEALTHCARE PHARMACEUTICALS
INC.; and JOHN DOES 1-100,

Defendants.

CIVIL ACTION NO: 9:14cv80831

JURY DEMANDED

COMPLAINT & JURY DEMAND

COMES NOW the Plaintiff, by and through the undersigned counsel, and hereby submits this Complaint against Defendants Janssen Research & Development, LLC f/k/a Johnson and Johnson PHARMACEUTICALS Research And Development LLC; Johnson & Johnson Company; Janssen Ortho, LLC; Janssen PHARMACEUTICALS, Inc. f/k/a Janssen PHARMACEUTICALS Inc., f/k/a Ortho-McNeil-Janssen PHARMACEUTICALS, Inc.; Bayer Corporation; Bayer AG; Bayer Healthcare, LLC; And Bayer Healthcare PHARMACEUTICALS, Inc.; and John Does 1-100,

(hereinafter collectively “Defendants”) for equitable relief, monetary restitution, and compensatory and punitive damages, arising from the injuries of Decedent as a result of his exposure to the PHARMACEUTICALS product Xarelto ® and hereby allege:

PARTIES

1. Decedent William N. Packard, Jr. (hereinafter “Decedent”) at all times relevant hereto, was a resident and citizen of the State of Florida. Decedent William N. Packard, Jr. suffered injuries, damages and death as a direct result of his ingestion of the PHARMACEUTICALS product Xarelto®.

2. Plaintiff Nancy Packard, at all times relevant hereto, was, and currently is, a resident and citizen of the State of Florida. Plaintiff Nancy Packard is the spouse and natural heir of Decedent and has standing to bring this action pursuant to Fla. Stat. §768.20 (hereinafter “Successor Plaintiff”).

3. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC (hereinafter "Janssen R & D"), f/k/a JOHNSON AND JOHNSON PHARMACEUTICALS RESEARCH AND DEVELOPMENT LLC, is a limited liability company organized, under the laws of New Jersey, with its principal place of business located at 920 U.S. Route 202, Raritan, New Jersey. 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 at all times relevant herein, engaged in the research, design, marketing, sale, and distribution of Xarelto®.

4. 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. At all times relevant herein, Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Xarelto®.

5. Defendant Janssen R & D is the holder of the approved New Drug Application ("NDA") for Xarelto®, as well as the supplemental NDA. Janssen R & D, Johnson & Johnson and Centocor all transact substantial business within the state of Florida and throughout the United States, including the research, manufacture, sale, distribution and marketing of Xarelto®, as set forth herein.

6. Defendant, JANSSEN ORTHO, LLC ("Ortho") is a Delaware limited liability company with a principal place of business in Puerto Rico. Ortho is a subsidiary of Johnson & Johnson. At all times relevant hereto, Defendant Ortho manufactures, and continues to manufacture Xarelto®. At all times relevant herein, Defendant Ortho derived, and continues to derive substantial revenue from goods and products developed, marketed, sold, distributed and disseminated and used in the state of Florida.

7. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICALS INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Janssen"), at all relevant times at the time suit was commenced, a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. At all times relevant and material hereto, Janssen was, and still is, a PHARMACEUTICALS company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of PHARMACEUTICALS, including Xarelto®.

8. Defendant BAYER CORPORATION ("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. Bayer Corp. transacts substantial business including the research, manufacture, sale, distribution and marketing of Xarelto® within the state of Florida and throughout the United States, as set forth herein.

9. Defendant, BAYER AG ("Bayer") is a foreign company with its principal place of business in Leverkusen, Germany, which licensed Xarelto®.

10. Defendant, BAYER HEALTHCARE LLC ("Bayer HC") is a Delaware limited liability company with its principal places of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205 and 100 Global View Drive, Warrendale, Pennsylvania. Bayer HC's sole member is Defendant Bayer Corporation.

11. Bayer HC is a subsidiary of Bayer and jointly developed Xarelto® with J&J and Janssen R&D. Bayer HC transacts substantial business including the research, manufacture, sale, distribution and marketing of Xarelto® within the state of Florida and throughout the United States, as set forth herein.

12. Bayer Healthcare PHARMACEUTICALS, Inc. ("Bayer Pharma") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Montville, New Jersey. Bayer Pharma is the U.S.-based PHARMACEUTICALS operation of Bayer HC, a division of Bayer. Bayer Pharma is a subsidiary of Bayer and jointly developed, marketed and distributed Xarelto® with J&J and Janssen R&D. At all times relevant and material herein, Bayer Pharma was, and still is, a PHARMACEUTICALS company involved in the manufacturing, distributing, sale and release for use to the general public of PHARMACEUTICALS, including Xarelto®.

13. Bayer's cooperation partner, J&J and Janssen R&D, submitted the new drug application for Xarelto® to the FDA.

14. Defendants Janssen R&D, J&J, Ortho, Janssen, Bayer, Bayer Corp., Bayer HC, and Bayer Pharma shall be referred herein individually by name or jointly as "Defendants."

15. 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.

16. 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.

17. 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.

18. At all times relevant and material hereto, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and or introducing into interstate commerce throughout the United States, and in the State of Florida, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the anti-coagulant PHARMACEUTICALS Xarelto®.

JURISDICTION AND VENUE

19. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds \$75,000.00 and the Plaintiff is a citizen of different states than the Defendants.

20. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district.

21. This is an action for damages, exclusive of interest and costs, which exceeds the sum of seventy-five thousand dollars (\$75,000.00).

NATURE OF THE CASE

22. Defendants, directly or by and through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold 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"), to treat pulmonary embolisms ("PE"), and/or to reduce the risk of recurrence of DVT and/or PE.

23. Defendants applied for an initial NDA for Xarelto® in July of 2008.

24. Xarelto® was approved by the Food and Drug Administration ("FDA") on July 1, 2011 to reduce the risk of blood clots, DVT, and PE following knee and hip replacement surgery. On November 4, 2011 Xarelto® was approved as an anti-coagulant primarily used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. On November 2, 2012 the FDA expanded the use of Xarelto® to the treatment of patients with DVT and PE, as well as long-term treatment to prevent recurrence of the same.

25. 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."¹

26. 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." The Defendants further claim that "it's been prescribed to more than seven million people around the world to help treat or reduce their risk of dangerous clots" and that it "begins working a few hours after you start taking it, and keeps working for as long as take it."²

27. 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."³

28. 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.⁴

29. Defendants claim that patients with AFib are 5 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."⁵

¹<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM357833>

² <http://www.xarelto-us.com/how-xarelto-works>

³ <http://www.xarelto-us.com/dvt-pe/treatment-of-dvt-pe>

⁴ <http://www.xarelto-us.com/dvt-pe/xarelto-difference#> and <http://www.xarelto-us.com/how-xarelto-is-different>

30. Rivaroxaban is an oxazolidinone derivative optimized for inhibiting both free Factor Xa and Factor Xa bound in the prothrombinase complex. It is a highly selective direct Factor Xa inhibitor with oral bioavailability and rapid onset of action. Inhibition of Factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated Factor II).

31. Defendants routinely marketed Xarelto® as a "one size fits all" drug. In their fervent marketing of Xarelto, Defendants' misinformed patients and their healthcare providers as to the necessity to routinely monitor any patient requiring a blood thinning agent. In essence, the Defendants have created a new drug, Xarelto®, that is not better than warfarin from a safety perspective, and at best, is only perhaps slightly easier to use and administer. 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.

32. The Defendants' marketing materials suggest that Xarelto® represented a therapeutic simplification and therapeutic progress because it did not require patients to undergo periodic monitoring with blood tests and because there were no dietary restrictions.

33. 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, states 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

⁵ <http://www.xarelto-us.com/knowning-your-stroke-risk>

conveyed in the boxed warning on the Xarelto® label.⁶

34. According to Institute for Safe Medication Practices, QuarterWatch Report, issued on October 3, 2012, the primary reported adverse event related to Xarelto® use "was not the well-understood risk of hemorrhage. Instead, the largest identifiable category was serious blood-clot-related injury--most frequently pulmonary embolism--the very events rivaroxaban is intended to prevent." This lack of efficacy for short term users of Xarelto® post hip and knee replacement surgery resulted in about 44% of the reported adverse effects from taking Xarelto®.

35. 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®.⁷ However, this information was not portrayed in the warning section on the warning label. The lack of efficacy of the medication for patients taking Xarelto® post hip and knee surgery were not disclosed resulting in patients ingesting Xarelto® and physicians prescribing Xarelto® without sufficient information to make an accurate decision.

36. 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.

37. 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 U.S. Food and Drug Administration (FDA) sending a letter stating that their print advertisement was

⁶ <http://www.xareltohcp.com/reducing-stroke-risk/safety.html>

⁷ <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm204091.htm>

"false or misleading because it minimizes the risks associated with Xarelto® and makes a misleading claim." Furthermore, the advertisement states "And there are no dosage adjustments" in conflict with the product labeling approved by the FDA.⁸

38. 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.⁹

39. 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.¹⁰

40. Due to the defective nature of Xarelto®, persons who were prescribed and ingested Xarelto®, for even a brief period of time, including the Decedent herein, were at increased risk for developing life-threatening bleeds. 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. 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."¹¹

41. Defendants' PHARMACEUTICALS Xarelto® led to 968 suspected undesirable side-effects

⁸<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM357833>, June 6, 2013 FDA Warning Letter

⁹http://www.huffingtonpost.com/2012/06/14/pradaxa-xarelto-blood-thinner-doctors-heart_n_1595971.html

¹⁰Frank 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-xarelto-idUSBRE9870AH20130908>

¹¹http://www.huffingtonpost.com/2012/06/14/pradaxa-xarelto-blood-thinner-doctors-heart_n_1595971.html

including 72 cases of death in Germany in just the first eight months of 2013.¹²

42. In addition, The Institute for Safe Medication Practices reported 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.”¹³

43. Even more significantly, in the first quarter of 2012, The Institute for Safe Medication Practices "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."¹⁴ 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."¹⁵ 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.

44. Defendants concealed their knowledge that Xarelto® can cause life threatening, irreversible bleeds from the Decedent, other consumers, the general public, and the medical community. The Defendants did not adequately warn of the irreversible nature of

¹² 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-xarelto-idUSBRE9870AH20130908>

¹³ Institute for Safe Medication Practices, QuarterWatch Report, October 3, 2012

¹⁴ *Id.*

¹⁵ *Id.*

Xarelto®. Specifically, Defendants did not adequately inform consumers and the prescribing medical community 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.

45. Moreover, Defendants failed to adequately warn about the lack of an antidote to reverse uncontrolled bleeding caused by Xarelto®. 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. Other safer alternatives to Xarelto® have an antidote that can reverse uncontrolled bleeding.

46. Importantly, Xarelto® still does not have a "black box" warning informing patients or prescribing doctors that Xarelto® can cause irreversible bleeds. In fact, a label change as recent as March 2014 still fails to contain a "black box" warning regarding irreversible bleeds.¹⁶

47. Aside from the warning labels, Defendants did not issue a Dear Doctor letter that sufficiently outlined the dangers of administering Xarelto® to a patient. In the September 2013 letter to healthcare professionals, Defendants do not mention the lack of an antidote in Xarelto® should serious and fatal bleeding occur while a patient was taking Xarelto®.

48. 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 the Decedent.

49. In addition to damages for the Defendants' inadequate warnings, Xarelto® also lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug.

¹⁶ http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022406s009lbl.pdf

50. Xarelto® is unreasonably dangerous and defective as formulated putting consumers, including Decedent, at an unreasonable risk of suffering needless injuries and death.

51. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds in users of Xarelto® to prevent any chances of their product's registrations being delayed or rejected by FDA.

52. As the manufacturers and distributors of Xarelto®, Defendants knew or should have known that Xarelto® use was associated with irreversible bleeds.

53. With the knowledge of the true relationship between use of Xarelto® and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings, or create an antidote, Defendants promoted and continue to promote Xarelto® as a safe and effective treatment for AFib.

54. According to the World Preview report, Defendants' "Xarelto® ... is estimated to be the 19th-best-selling drug in the world by 2018" and "Worldwide sales of Xarelto® are expected to jump from \$596 million in 2012 to \$3.7 billion in 2018."¹⁷

55. While Defendants enjoy great financial success from their expected blockbuster drug, Xarelto®, they continue to place American citizens at risk of severe bleeds and death.

56. Consumers, including Decedent, William N. Packard, Jr., who have used Xarelto® to reduce the risk of stroke due to Afib or to reduce the risk of blood clots, particularly DVT and PE, following knee or hip replacement surgery, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with Xarelto® therapy.

57. Defendants, through their affirmative misrepresentations and omissions, actively

¹⁷ <http://www.drugwatch.com/2013/07/23/blood-thinner-growth-more-risk/>

concealed from Decedent and Decedents physicians the true and significant risks associated with Xarelto® use.

58. As a result of Defendants' actions, Decedent and Decedent's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Decedent's Xarelto® use were the direct and proximate result of Defendants' conduct.

FACTUAL ALLEGATIONS

59. On or around January 10, 2012, Decedent was first prescribed and began taking Xarelto® upon direction of his physician for atrial fibrillation. Subsequently, as a direct result of Decedent's ingestion of Xarelto®, Decedent suffered a subdural hemorrhage leading to the death of Decedent on or about June 28, 2012.

60. Decedent was admitted on or about June 23, 2012 for several days to Abington Memorial Hospital in Abington, Pennsylvania, where he underwent a right frontal bur hole with evacuation in an attempt to stop the subdural bleeding that ultimately caused and/or contributed to Decedent's death.

61. As a direct result of being prescribed Xarelto® for this period of time, Decedent suffered significant injuries and death, such as those described above.

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

63. Decedent would not have used Xarelto® had Defendants properly disclosed the risks associated with its use, as safer alternatives without the aforesaid risks were available.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATION

64. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

65. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through failing to disclose, for three years, the truth about the safety and efficacy of Xarelto®, to Decedent's physicians and/or Decedent, and 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.

66. Decedent had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Decedent could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action.

67. Decedent, nor Decedent's physicians, could have possibly determined the nature, extent and identity of related health risks associated with Xarelto®. Decedent and Decedent'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.

68. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of Xarelto®. Defendants were under a duty to disclose the true character, quality, and nature of Xarelto® because this was nonpublic information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew this information was not available to the Decedent or his physicians. In addition, the Defendants are estopped from relying on any statute of limitations

because of their concealment of these facts.

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

COUNT I
STRICT PRODUCTS LIABILITY- FAILURE TO WARN

Comes now Plaintiff and for Count I of this Complaint alleges:

69. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

70. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count I of this complaint for the wrongful death of William F. Packard, Jr.

71. Plaintiff has standing to prosecute this action pursuant to Fla. Stat. §768.20.

72. Defendants owed a duty of reasonable care to adequately warn of the risks associated with the use of Xarelto® to Decedent and the general public.

73. Defendants knew or reasonably should have known that the warnings provided to users of Xarelto® regarding the risks associated with its use were incorrect and misleading in at least the following material respects:

- a. Xarelto® was unaccompanied by proper warnings regarding all possible side effects associated with its use and the comparative severity, incidence, and duration of such adverse effects; and
- b. Xarelto® was defective due to inadequate post-marketing warnings or instructions, because Defendants failed to provide adequate warnings to users or

consumers and continued aggressively to promote Xarelto®, even after it knew or should have known of the risks of injury from this drug; and

- c. Xarelto® was unaccompanied by proper warnings regarding irreversible bleeding caused by Xarelto® and Defendants continued to aggressively promote Xarelto®, even after it knew of should have known of the risk of irreversible bleeding from this drug; and
- d. Defendants failed to warn that there were other drugs available that did not have the same risks as Xarelto®.

74. By failing to warn Decedent and Decedent's physicians of the adverse health risks associated with Xarelto®, Defendants breached their duty to Decedent of reasonable care and safety.

75. Defendants, as manufacturers and distributors of PHARMACEUTICALS drugs, 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.

76. Decedent did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Decedent or to Decedent's treating physicians.

77. Defendants had a continuing duty to provide consumers, including Decedent

and Decedent'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.

78. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Xarelto®, to health care providers empowered to prescribe and dispense Xarelto® to consumers, including Decedent, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Xarelto®, which resulted in injury and death to Decedent.

79. Despite the fact that Defendants knew or should have known that Xarelto® caused unreasonable and dangerous side effects, they continued to promote and market Xarelto® without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

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

81. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Decedent, and to Decedent's intermediary physicians, in the following ways:

- a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Decedent and Decedent's physicians to the dangerous risks of Xarelto® including, among other things, irreversible bleeds;

- b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, irreversible bleeds;
- c. Defendants continued to aggressively promote and sell Xarelto®, even after they knew or should have known of the unreasonable risks of irreversible bleeds from this drug.

82. Defendants had an obligation to provide Decedent and Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Xarelto®, and/or that there existed safer and more or equally effective alternative drug products.

83. By failing to provide Decedent and Decedent's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Xarelto®, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

84. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Decedent and the general public.

85. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto® was a proximate cause of Decedent's injuries and damages.

86. Plaintiff seeks all damages to which they may be justly entitled.

87. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

Comes now Plaintiff and for Count II of this Complaint alleges:

88. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

89. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count II of this complaint for the wrongful death of William F. Packard, Jr.

90. At all times material to this lawsuit, Defendants were engaged in the business of designing, manufacturing, testing, marketing, distributing and selling Xarelto® for the sale to, and use by, members of the public. The Xarelto® manufactured by Defendants reached Decedent without substantial change and was ingested as directed. The Xarelto® was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Decedent.

91. Defendants sold the Xarelto® which was ingested by Decedent.

92. Defendants owed a duty to the general public, and specifically to the Decedent, to exercise reasonable care in the design, study, development, manufacture, promotion; sale, marketing and distribution of their prescription medications, including the Xarelto® at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Xarelto® because as designed, Xarelto was capable of causing serious personal injuries such as those suffered by Decedent during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Xarelto® because they failed to warn, that as designed, Xarelto® was capable of causing serious personal injuries such as those suffered by Decedent during foreseeable

use.

93. 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.

94. The Xarelto® ingested by Decedent was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Decedent. Any benefit of Xarelto® was far outweighed by the serious and undisclosed risks of its use, and other drugs performed the same function without the increased risks of Xarelto®.

95. The Xarelto® ingested by Decedent was defective at the time it was distributed by the Defendants or left their control.

96. Decedent was a person who would reasonably be expected to use Xarelto®.

97. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto® was a proximate cause of Decedent's injuries and damages.

98. Plaintiff seeks all damages to which they may be justly entitled.

99. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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
NEGLIGENCE

Comes now Plaintiff and for Count III of this Complaint alleges:

100. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

101. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count I of this complaint for the wrongful death of William F. Packard, Jr.

102. At all times relevant and material hereto, Defendants owed a duty to Decedent of reasonable care and safety.

103. Defendants owed a duty to the general public, and specifically to the Decedent, 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 Decedent during foreseeable use.

104. Defendants' duties included, but were not limited to, carefully and properly designing, testing, manufacturing, licensing, packaging, promoting, advertising, selling, and/or distributing Xarelto® into the stream of commerce, and providing warnings with regard to this drug.

105. Defendants breached their duty of care and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Decedent:

- 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 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 shouldn't 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. Failing to use ordinary care in designing, testing, and manufacturing Xarelto® so as to avoid the high risk to users of unreasonable, dangerous side-effects, some of which are fatal;
 - h. Failing to accompany Xarelto® with adequate warnings that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of this drug and the nature, severity and duration of such adverse effects;
 - i. Failing to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of Xarelto®;
 - j. Defendants were otherwise careless or negligent.

106. The Xarelto® that injured Decedent was in substantially the same condition when Decedent ingested it as it was in when it left the control of Defendants. Xarelto®'s

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

107. Although Defendants knew or should have known that Xarelto® caused unreasonably dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market this drug to doctors when there were safer and less expensive alternatives available.

108. In addition, Defendants had a legal duty to comply with the U.S. Food, Drug and Cosmetic Act, U.S. Code § 21 USC §301, et seq., and regulations promulgated there under.

109. Defendants negligently and carelessly violated the laws and regulations of the United States including, but not limited to the following: 21 CFR §330.10(a)(4)(v) (Labeling); 21 CFR § 369.10 (Labeling); 21 CFR §§ 201.56 and 201.57 (d), (e) and (f) (Labeling); 21 CFR 1.21 (a) (Labeling); 21 CFR 600.80 (Post-marketing Reporting of Adverse Experiences); 21 CFR §314.50 (Post Marketing Reports of Adverse Drug Experiences), as well as regulations relating to the promotion of drugs for unlabeled uses. The violations of those and other statutes and regulations constitute negligence per se.

110. Defendants owed a duty to the general public, and specifically to the Plaintiff Decedent, to exercise reasonable care in the design, study, development, manufacture, promotion; sale, marketing and distribution of their prescription medications, including the Xarelto® at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Xarelto® because as designed, Xarelto was capable of causing serious personal injuries such as those suffered by Decedent during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Xarelto® because they failed to warn, that as designed, Xarelto® was capable of

causing serious personal injuries such as those suffered by Decedent during foreseeable use.

111. Defendants breached their duty and were negligent in, but not limited to, the following actions, misrepresentations, and omissions toward Decedent:

- 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. 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;
- c. In disseminating information to Decedent and Decedent's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Decedent;
- d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of irreversible bleeds;
- e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
- f. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto®;
- g. Failing to warn Decedent, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Decedent and other consumers;

- h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Xarelto® and patients taking Xarelto®;
- i. 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®;
- j. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent or antidote;
- k. In designing, manufacturing, 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 Decedent;
- l. 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;
- m. 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
- n. Representing to physicians, including but not limited to Decedent's prescribing physicians, that this drug was safe and effective for use.

112. The Xarelto® that injured Decedent was in substantially the same condition when Decedent ingested it as it was in when it left the control of Defendants. Defendants' Xarelto®'s ability to cause serious personal injuries and damages, such as those suffered by Decedent, was not due to any voluntary action or contributory negligence of Decedent. Decedent consumed the Xarelto® as directed and without change in its form

or substance.

113. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto® was a proximate cause of Decedent's injuries and damages.

114. Plaintiff seeks all damages to which they may be justly entitled.

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

116. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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- FAILURE TO WARN

Comes now Plaintiff and for Count IV of this Complaint alleges:

117. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

118. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count IV of this complaint for the wrongful death of William F. Packard, Jr.

119. Defendants owed a duty to warn of any dangerous defects or side effects; a duty to assure their product did not cause users unreasonable and dangerous risks, reactions, and side

effects; and a duty to provide adequate post market surveillance and warnings as it learned of Xarelto®'s substantial dangers.

120. 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.

121. Decedent was prescribed and used Xarelto® for its intended purpose.

122. Decedent could not have known about the dangers and hazards presented by Xarelto®.

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

124. The warnings, or lack thereof, that were given by the 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.

125. The warnings that were given by the Defendants failed to properly warn Decedent and prescribing physicians of the prevalence of irreversible bleeds.

126. The Decedent, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants. The Defendants had a continuing duty to warn the Decedent and prescribing physicians of the dangers associated with Xarelto®. Had Decedent received adequate warnings regarding the risks of Xarelto®, he would not have used Xarelto®.

127. Defendants breached their duty of reasonable care to Decedent in the following material respects:

a. Xarelto® was unaccompanied by proper warnings regarding all possible side effects associated with its use and the comparative severity, incidence, and duration of such adverse effects; and

b. Xarelto® was defective due to inadequate post-marketing warnings or instructions, because Defendants failed to provide adequate warnings to users or consumers and continued aggressively to promote Xarelto®, even after Defendants knew or should have known of the risks of injury from this drug; and

c. Xarelto® was unaccompanied by proper warnings regarding irreversible bleeding caused by Xarelto® and Defendants continued to aggressively promote Xarelto®, even after Defendants knew or should have known of the risk of irreversible bleeding from this drug; and

d. Defendants failed to warn that there were other drugs available that did not have the same risks as Xarelto®.

128. Defendants knew or should have known that Xarelto® caused unreasonably dangerous risks and side effects of which the general public would not be aware. Defendants nevertheless advertised, marketed, and promoted their product knowing there were safer products on the market.

129. Defendants knew that 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 the Defendant's knowledge of the increased risk of these injuries over other anticoagulation therapies available.

130. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto® was a proximate cause of Decedent's injuries and damages.

131. Plaintiff seeks all damages to which they may be justly entitled.

108. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

132. For the above reasons, the Defendants are strictly liable under Florida product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff demands judgment against Defendants 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- NEGLIGENT DESIGN

Comes now Plaintiff and for Count V of this Complaint alleges:

133. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

134. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count V of this complaint for the wrongful death of William F. Packard, Jr.

135. Defendants designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the PHARMACEUTICALS drug Xarelto®, which Defendants knew would be used by Decedent and others.

136. At the time Xarelto® was manufactured and sold to Decedent by Defendants, it was defective in design and unreasonably dangerous, subjecting users to risks of blood clots and irreversible bleeding which exceeded the benefits of the products, and for which other safer products were available.

137. Alternatively, when Xarelto® was manufactured and sold to Decedent by Defendants, the product was defective in design and formulation, making use of the product more dangerous than other drugs for its intended use.

138. The Xarelto® sold to Decedent reached him without substantial change. Decedent was unaware of the dangerousness of the product until after its use. Decedent ingested the Xarelto® without making any changes or alterations.

139. In designing and testing Xarelto®, the Defendants failed to exercise the ordinary care that a careful and prudent drug manufacturer would exercise in the same or similar circumstances.

140. As a direct and proximate result of the negligent design of Xarelto®, Plaintiff has been damaged.

141. Defendants' conduct was done with conscious disregard for the safety of users of Xarelto®, including Decedent, justifying an award of punitive damages.

142. Plaintiff seeks all damages to which they may be justly entitled.

143. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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
Negligent Misrepresentation

Comes now Plaintiff and for Count VI of this Complaint alleges:

143. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

144. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count VI of this complaint for the wrongful death of William F. Packard, Jr.

145. Defendants knew, or should have known, that there were dangerous side effects resulting from the use of Xarelto®.

146. Defendants knew or reasonably should have known that consumers such as Decedent would not have known about the increased risk of irreversible bleeds, among other things, associated with Xarelto®.

147. Defendants, armed with the knowledge stated in the preceding paragraphs, proceeded with the design, production, manufacture, promotion, advertising, and sale of Xarelto® without adequate warning of the side effects and dangerous risks to the consuming public, including Decedent.

148. Defendants negligently represented to Decedent the safety and effectiveness of Xarelto® and concealed material information, including adverse information regarding the safety and effectiveness of Xarelto®. The misrepresentations and/or material omissions made by or perpetuated by Defendants are as follows:

- a. Defendants failed to conduct sufficient testing which, if properly performed, would have shown that Xarelto® had serious side effects, and warn users of those

risks; and/or

- b. Include adequate warnings with Xarelto® that would alert users to the potential risks and serious side effects of Xarelto®, as well as the limited benefits and the approved uses; and/or
- c. Warn Decedent that use of Xarelto® carried a risk of death or permanent injury from irreversible bleeding, and other serious side effects; and/or
- d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Xarelto®.

149. Defendants made the misrepresentations and omissions with the intent that Decedent and the consuming public rely upon such information or the absence of such information in selection of Xarelto®.

150. Decedent justifiably relied on and/or was induced by the misrepresentations and/or active concealment by Defendants and relied upon the absence of safety information, which Defendants suppressed, concealed, or failed to disclose, all to his detriment.

151. As a direct and proximate result of the dangerous and defective condition of Xarelto®, Decedent was injured, and incurred economic damages in the form of medical and funeral expenses.

152. Plaintiff is entitled to recover from Defendants for all damages caused by the defective product including, but not limited to, damages for pain, suffering, loss of the capacity to enjoy life, lost past and future income and occurred expense, and death.

WHEREFORE, Plaintiff demands judgment against Defendants 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
BREACH OF WARRANTY- BREACH OF EXPRESS WARRANTY

153. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

154. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count VII of this complaint for the wrongful death of William F. Packard, Jr.

155. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released into the stream of commerce Xarelto®, in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Decedent, or persons responsible for consumer.

156. Xarelto® materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Xarelto®, respectively manufactured and/or distributed and sold by Defendants, and which Decedent purchased and ingested in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Decedent concerning Xarelto® sold to Decedent.

157. Defendants breached these express warranties in that Xarelto® was unsafe in light of the risk of life-threatening side effects associated with its use, including irreversible bleeds

158. Decedent relied to his detriment on Defendants' express warranties.

159. As a direct, foreseeable, and proximate result of Defendants' breaches of express warranties, Decedent suffered grievous bodily injury and consequent economic and other loss, as described above, when Decedent's physician, in reasonable reliance upon such express warranties, prescribed for Decedent the use of Xarelto®. Decedent

purchased and ingested Xarelto® as prescribed and instructed by Decedent's physician, leading to Decedent's injuries.

160. As a direct and proximate result of Defendants' breach of express warranties, Decedent was exposed to Xarelto®, and Plaintiff and Decedent suffered and continues to suffer from the injuries and damages as set forth in this Complaint.

WHEREFORE, Plaintiff demands judgment against Defendants 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
BREACH OF WARRANTY- BREACH OF IMPLIED WARRANTY

161. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

162. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count VIII of this complaint for the wrongful death of William F. Packard, Jr.

163. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released into the stream of commerce Xarelto®, in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Decedent, or persons responsible for consumer.

164. Defendants impliedly warranted their Xarelto®, which they manufactured and/or distributed and sold, and which Decedent purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

164. Defendants breached their implied warranties of Xarelto® sold to Decedent because this product was not fit for its common, ordinary, and intended use.

166. As a direct, foreseeable and proximate result of Defendants' breaches of

Implied warranties, Decedent suffered grievous bodily injury and consequential economic and other losses, as described above, when Decedent ingested Xarelto®, in reasonable reliance upon the implied warranties, leading to Decedent's injuries.

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

168. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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
FRAUD

169. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

170. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count IX of this complaint for the wrongful death of William F. Packard, Jr.

171. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of Xarelto® described herein, owed a duty to provide accurate and complete information regarding these products.

172. The Defendants knew or should have known, that Xarelto® was unreasonably dangerous and defective, and caused serious, at times fatal, irreversible bleeds.

173. Despite their knowledge, the Defendants omitted material facts in the disclosures

they made to the public, the medical community and to consumers, including the Decedent and prescribing physicians, concerning the use and safety of Xarelto®.

174. The Defendants made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Decedent and prescribing physicians, concerning the use and safety of Xarelto®.

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

176. The 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.

177. The Defendants' statements and omissions were made with the intent that the Decedent and his prescribing physician, would rely on them.

178. The Decedent 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.

179. As a direct and proximate result of the Defendants' acts of fraud, the Decedent suffered irreparable injuries.

180. Decedent endured substantial pain and suffering. As a result, the Decedent and Plaintiff incurred significant expenses for medical care and will continue to be economically and emotionally harmed in the future.

181. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent was exposed to Xarelto® and suffered the injuries and damages set forth hereinabove.

WHEREFORE, Plaintiff demands judgment against Defendants 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:
VIOLATION OF CONSUMER PROTECTION LAWS

182. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

183. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count X of this complaint for the wrongful death of William F. Packard, Jr.

184. Decedent 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.

185. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

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

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

187. 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 Decedent in the marketing and advertising campaign described herein.

188. 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®.

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

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

COUNT XI:
PUNITIVE DAMAGES

190. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

191. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count XI of this complaint for the wrongful death of William F. Packard, Jr.

192. Plaintiffs are entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety. Defendants mislead both the medical community and the public at large, including Decedent and Decedent's physicians, by making false representation about and concealing pertinent information regarding

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

193. As a proximate result of Defendants' acts and omissions, Decedent suffered internal bleeding/hemorrhaging, all resulting from Decedent's ingestion of Xarelto®.

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

195. Defendants continued to promote the safety of Xarelto®, while providing to consumers no warnings or insufficient warnings about the risk of irreversible bleeding associated with it, even after Defendants knew of that risk.

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

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

COUNT XII:
WRONGFUL DEATH

197. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

198. Plaintiff, Nancy Packard, individually and as successor in interest of William F. Packard, Jr., brings Count XII of this complaint for the wrongful death of William F. Packard, Jr.

199. Successor Plaintiffs have the right to bring the following survival action on behalf of

of William F. Packard, Jr. under Florida Statute.

200. At all times material hereto, Defendants owed a duty to Decedent to protect Decedent against reasonably foreseeable harms that a prudent person would anticipate were likely to result from the Defendants' acts or omissions.

201. Defendants breached that duty when they acted in the negligent and/or tortious manner set forth in paragraphs above.

202. Defendants' negligent and tortious conduct was the direct and proximate cause of Decedent's death on June 28, 2012.

203. If death had not ensued, Decedent would have been entitled to maintain a cause of action and recover damages against Defendants because of the above alleged negligent and tortious conduct.

204. As a direct, foreseeable and proximate result of Defendants' conduct, Decedent's estate has incurred medical and funeral and burial expenses.

205. As a direct, foreseeable and proximate result of the Defendants' conduct, Decedent's estate has been deprived of prospective net accumulations and loss of earnings.

206. In addition, Plaintiffs demand payment for all economic losses suffered by the Decedent's survivors, including costs of administration and other expenses reasonably associated with the Decedent's death.

207. The claims for Wrongful Death, Survival and/or those other claims available under applicable law, set forth herein are hereby asserted on behalf of all persons having such claims, including Decedent's surviving spouse and surviving children.

208. Plaintiffs claim damages of Defendants under and by virtue of the Florida's

Wrongful Death Statute for the pecuniary value of future services, support, society, comfort, and contribution of the Decedent that would have been rendered to the wrongful death beneficiaries for the expected remainder of their lives.

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiff demands judgment for damages against Defendant for all damages allowable by law against Defendants together with interest, costs and attorney's fees, including but not limited to those damages provided pursuant to applicable law, set forth below, and requests a trial by jury of all issues so triable, to wit:

- a) 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 Decedent as a result of ingesting Defendants' Xarelto®;
- b) The value of lost support and services from the date of the Decedent's injury to the date of death, with interest, and future loss of support and services from the date of death and reduced to present value;
- c) As to the surviving spouse, individually, losses as a surviving spouse of decedent, including, for loss of companionship, protection, contribution and for mental pain and suffering from the date of injury;
- d) Medical or funeral expenses due to the decedent's injury or death may be recovered;
- e) Any and all loss of earnings of the deceased from the date of injury to the date of death, less lost support of survivors excluding contributions in kind, with interest;
- f) Loss of the prospective net accumulations of an estate, which might reasonably have been expected but for the wrongful death;

- g) Medical or funeral expenses due to the decedent's injury or death that have become a charge against the estate;
- h) Punitive damages in an amount to be awarded as provided by law; and
- i) For all other just and proper relief.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Respectfully submitted this 23rd day of June, 2014.

By: /s/ Neil D. Overholtz

Neil D. Overholtz

Florida Bar No.: 0188761

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC

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