UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	MDL No. 2592 SECTION: L JUDGE FALLON MAG. JUDGE NORTH
Mary Lou Garza, individually and Executrix of the ESTATE of ISRAEL M. GARZA Plaintiff, vs. JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; JANSSEN ORTHO, LLC; JANSSEN PHARMACEUTICALS, INC, f/k/a JANSSEN PHARMACEUTICA INC, f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC; BAYER HEALTHCARE PHARMACEUTICALS, INC; BAYER PHARMA AG; BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE AG; and BAYER AG; Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.: 2:15-cv-15-1699

SUMMARY OF PLAINTIFF'S ALLEGATIONS

This action arises from the wrongful death of Israel Garza caused by the ingestion of Xarelto®. Mary Lou Garza brings this action as the surviving spouse and Executrix of the Estate of Israel Garza, against the captioned Defendants, jointly and severally, on the

grounds and in the amount as hereinafter set forth. Mr. Garza, Mrs. Garza, and the Estate of Israel Garza shall be referred to herein by name, or together as "Plaintiff" or "Ingesting Plaintiff."

1. Plaintiff suffered damages as a result of Defendants' wrongful conduct in connection with the development, design, testing, manufacture, distribution, and sale of Xarelto®. Plaintiff suffered damages as a direct result of his ingestion of Xarelto®.

2. This action is brought on behalf of Plaintiff who used Xarelto®, also known as rivaroxaban, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE"), to reduce the risk of recurrence of DVT and/or PE, and/or for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

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

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

5. Defendants concealed their knowledge of Xarelto's® defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

6. 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 and other patients throughout the United States of America.

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

8. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer to suffer serious and dangerous side effects including, *inter alia*, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences and death. Plaintiff has sustained certain of the above health consequences due to Plaintiff's ingestion and use of Xarelto®.

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

10. As a result of the inadequate development, design, testing, manufacture, distribution, and sale of Xarelto® sold by Defendants and ingested by Plaintiff, Plaintiff has suffered, and continues to suffer, serious bodily injury and death.

PARTIES

11. Plaintiff, Mary Lou Garza, is the surviving spouse and Executrix of the Estate of Israel M. Garza, deceased, per Mr. Garza's Last Will and Testament. Mrs. Garza brings this case as the Executrix, and in her own name as spouse, both suffering damages, including but not limited to Mr. Garza's wrongful death, as a direct result of his ingestion of Xarelto®.

12. At all times relevant hereto, Mr. Garza and Mrs. Garza were/are resident(s) and citizens of the State of Texas, Duval County, residing at 402 Stinson Street, Freer TX 78357.

13. Mr. Garza died in a hospital in Corpus Christi, TX on or about May 19, 2013 suffering damages and wrongful death as a direct result of his ingestion of Xarelto®.

14. The Estate of Israel Garza, deceased, is in probate proceedings in Duval County Court, TX, Case No. 15-3132. Ms. Garza bring this wrongful death action pursuant to Tex. Civil Practice and Remedies Code, § 71.001 *et seq.*

15. Plaintiff anticipates joining other similarly situated plaintiffs in this action because each of the other plaintiffs' claims, named and un-named, are logically related to each other. Plaintiffs' claims and rights to relief arise out of the same transactions and series of transactions including but not limited to the design, testing, manufacture, marketing, distribution and sale of Xarelto®.

16. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC ("J&J") is a limited liability company organized, under the laws of New Jersey, with corporate headquarters located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey, 08933. Defendant J&J is the holder of the approved New Drug Application ("NDA") for Xarelto® as well as the supplemental NDA.

17. As part of its business, J&J is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto® and rivaroxaban.

18. Upon information and belief, Defendant J&J has transacted and conducted business in the State of Texas.

19. Upon information and belief, Defendant J&J has derived substantial revenue from good and products used in the State of Texas.

20. Upon information and belief, Defendant J&J expected or should have expected its acts to have consequence within the United States of America and the State of Texas,

and derived substantial revenue from interstate commerce within the United States and the State of Texas, more particularly.

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

22. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

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

24. Upon information and belief, Defendant, JANSSEN ORTHO has transacted and conducted business in the State of Texas.

25. Upon information and belief, Defendant, JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of Texas.

26. Upon information and belief, Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequence within the United States of America and the

State of Texas, and derived substantial revenue from interstate commerce within the United States and the State of Texas, more particularly.

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

28. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

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

30. Upon information and belief, Defendant JANSSEN PHARM has transacted and conducted business in the State of Texas.

31. Upon information and belief, Defendant JANSSEN PHARM has derived substantial revenue from goods and products used in the State of Texas.

32. Upon information and belief, Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the

State of Texas, and derived substantial revenue from interstate commerce within the United States and the State of Texas, more particularly.

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

34. Defendant BAYER CORPORATION ("Bayer Corp") is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Road Pittsburgh, Pennsylvania. Upon information and belief, Defendant Bayer Corp is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

35. At relevant times, Defendant Bayer Corp was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto®.

36. At relevant times, Defendant Bayer Corp conducted regular and sustained business in the State of Texas by selling and distributing its products in the State of Texas and engaged in substantial commerce and business activity in this State and through interstate commerce within the United States of America.

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

38. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

39. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. Upon information and belief, Bayer Schering Pharma AG was then renamed BAYER PHARMA AG effective July 1, 2011.

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

41. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of Texas.

42. Upon information and belief, Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of Texas.

43. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America

and the State of Texas, and derived substantial revenue from interstate commerce within the United States and the State of Texas, more particularly.

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

45. Defendant, BAYER HEALTHCARE LLC ("Bayer HC") is a limited liability company with corporate communication headquarters located at 100 Bayer Road, Pittsburgh, PA 15205. Bayer HC's North American Headquarters are located at 100 Bayer Blvd, Whippany, NJ 07981. Bayer HC is a subsidiary of Bayer and jointly developed Xarelto® with J&J. Bayer's cooperation partner, J&J, submitted the new drug application for Xarelto® to the FDA.

46. Upon information and belief, at all relevant times, Defendant Bayer HC expected or should have expected that its acts would have consequences within the United States of America, in the State of Texas, and derived substantial revenue from interstate commerce.

47. Upon information and belief, at all relevant times, Defendant Bayer HC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto® for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-

valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

48. Defendant, 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 at 100 BAYER BLVD, WHIPPANY, NJ 07981. 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 Xarelto® with J&J. 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 Texas and throughout the United States.

49. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMAAG.

50. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Texas, and derived substantial revenue from interstate commerce.

51. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Texas, and derived substantial revenue from interstate commerce.

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

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

54. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent holding company of all other Bayer-named Defendants.

55. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Texas, and derived substantial revenue from interstate commerce.

56. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Texas, and derived substantial revenue from interstate commerce.

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

58. Bayer's cooperating partner, Defendant J&J, submitted the new drug application to the FDA for Xarelto®.

59. Together, each of the named defendants shall be referred to by name or jointly as the "Defendants."

60. At all times alleged herein, Defendants shall include any and all named or un-named 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.

61. 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.

62. 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.

63. 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, including the State of Texas, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the anti-coagulant pharmaceutical Xarelto®.

JURISDICTION AND VENUE

64. This Court has jurisdiction over Defendants because each regularly conducts business, receives substantial revenues, markets and sells, and performs services in Texas and through interstate commerce in the United States. At all times material and relevant hereto, Defendants were each involved in the development of the pharmaceutical drug Xarelto® for distribution, sale, or intended use throughout the United States, including Texas. Accordingly, Defendants each conducted business within the State of Texas. A substantial part of Defendants' acts, omissions and events give rise to Plaintiff's personal injuries in the State of Texas.

65. Jurisdiction is proper in the United States District Court pursuant to 28 U.S.C. § 1332(a)(1) based on diversity because Plaintiff is a resident of the State of Texas while each Defendant is a resident of another state as set forth above. Furthermore, this is an action for damages, exclusive of interest and costs, which exceeds the sum of seventy-five thousand dollars ($75,000.00).

66. This Court has jurisdiction over the Defendants pursuant to the Judicial Panel on Multidistrict Litigation's Order of December 12, 2014, and consistent with both the laws of the State of Texas and Federal Constitutional requirements of Due Process in so far as Defendants, acting through agents or apparent agents, committed one or more of the following:

i. Defendants transacted, and continue to transact, business in Texas, and conducted, and regularly conducts business, receives substantial revenues, and sells and performs services in Texas and the United States; and

ii. Requiring Defendants to litigate this claim, and other claims arising for similar circumstances, transactions or occurrences, in MDL No. 2592, does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

67. For pre-trial proceedings, venue is proper in MDL No. 2592 pursuant to the Judicial Panel on Multidistrict Litigation's Order of December 12, 2014. Venue is also proper for pre-trial proceedings in the United States District Court in the Eastern District of Louisiana pursuant to Pre-Trial Order No. 9 (Doc. No. 356) entered by the Honorable Eldon E. Fallon in MDL No. 2592 on March 24, 2015.

68. For trial, venue is proper in the United States District Court for the Southern District of Texas, Corpus Christi Division, pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to this action occurred therein. For example, within the United States District Court for the Southern District of Texas, Corpus Christi Division, Ingesting Plaintiff: (i) Was prescribed Xarelto® in Alice, Tx, Jim Wells County; (ii) Died in Corpus Christi, Tx, Nueces County; (iii) Resided in Freer, Tx, Duval County; (iv) upon information and belief, purchased Xarelto®; and (v) because Defendants marketed, distributed, and sold Xarelto® within the Southern District of Texas.

NATURE OF THE CASE - GENERAL ALLEGATIONS

69. 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.

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

71. Xarelto® was approved by the Food and Drug Administration ("FDA") on July 1, 2011 reduces 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.

72. 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]

73. 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

[1] http://www.fda.gov/downloadslDrugs/GuidanceComplianceRegulatorylnformationiEnforcement ActivitiesbyFDAIWarningLettersandNoticeofViolationLetterstoPharmaceuticaiCompanies/UCM357833.pdf

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] In spite of these representations, Defendants also fail to include reasonable or adequate warnings relating to the use of Xarelto® by patients with AFib, potentially caused by a heart valve problem such as aortic stenosis and mitral stenosis in the Prescribing Information and/or marketing materials.

74. 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]

75. 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]

76. 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]

77. 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

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[2] 2 http://www.xarelto-us.com/how-xarelto-works

[3] http://www.xarelto-us.comldvt-pe/treatment-of-dvt-pe

[4] http://www.xarelto-us.comldvt-pe/xarelto-difference# and http://www.xarelto-us.com/how-xarelto- is-different

[5] http://www.xarelto-us.comlknowing-your-stroke-risk

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).

78. 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, 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.

79. 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.

80. 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. [6]

[6] http://www.xareltohcp.com/reducing-stroke-risklsafety.html

81. According to Institute for Safe Medication Practices, Quarter Watch 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-c1ot- 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®.

82. 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.

83. 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.

84. 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

[7] http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm204091.htm

the U.S. Food and Drug Administration (FDA) to send an untitled letter stating that their 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. [8]

85. 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]

86. 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]

87. Due to the defective nature of Xarelto®, persons who were prescribed and ingested Xarelto®, for even a brief period of time, including the Ingesting Plaintiff 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

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[8] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Enforcement ActivitiesbyFDNWarningLettersandNoticeofViolationLetterstoPharmaceuticaiCompanies/UCM357 833.pdf, June 6, 2013 FDA Untitled Warning Letter

[9] Ransdell Pierson. "Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners" HujJpost Healthy Living. 14thJune 2012.

[10] Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" http://www.reuters.comlarticle/20 13/09/08/us-bayer-xarelto- idUSBRE9870AH20 130908

health care professionals] stress that neither new drug [Xarelto] has a known antidote for a bleeding emergency, as warfarin does."[11]

88. Defendants' pharmaceutical Xarelto led to 968 suspected undesirable side-effects including 72 cases of death in Germany in just the first eight months of2013.[12]

89. 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]

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

90. 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

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

[12] Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" http://www.reuters.com/article/20 13/09/08/us-bayer-xarelto- idUSBRE9870AH20 130908

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

[14] Id.

[15] Id.

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.

91. Defendants concealed their knowledge that Xarelto® can cause life threatening, irreversible bleeds from the Ingesting Plaintiff, other consumers, the general public, and the medical community. 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

- *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)*

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.

92. 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 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 (rFVIIA) may be considered but has not been evaluated in clinical trials." However, this is buried in small print.

93. Importantly, Xarelto® still does not have a "black box" warning informing patients or prescribing doctors know that Xarelto® can cause irreversible bleeds. In fact, the August 2013 Highlights of Prescribing Information only has a "black box" warning stating the following:

WARNING: (A) PREMATURE DISCONTlNUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS. and (B) SPINAL/EPIDURAL HEMATOMA See full prescribing information for complete box 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 paralvsis (5.2.5.3,6.2.),
Monitor patients frequently for signs and syptoms of neurological impairment and it observed, treat urgently. Consider the benefits and risks before neuraxial intervention in

patients who are or who need to be anticoagulated (5.3).

94. 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. 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)*

95. 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®.

96. 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 Ingesting Plaintiff herein.

97. Even if the warnings were sufficient, which Ingesting Plaintiff strongly denies, Xarelto® still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug. Xarelto® is quite simply dangerous and defective as formulated. The Defendants should withdraw Xarelto® from the market.

98. 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.

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

100. 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.

101. Defendants' "Xarelto® … is estimated to be the 19th-best-selling drug in the world by 2018, according to the report. Worldwide sales of Xarelto® are expected to jump from $596 million in 2012 to $3.7 billion in 2018."[16]

102. 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.

[16] http://www.drugwatch.coml20 13/07 123/blood-thinner-growth-more-risk

103. Consumers, including Ingesting Plaintiff, Israel M. Garza, who have used Xarelto® to reduce the risk of stroke due to Afib or to reduce the risk of blood clots, 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.

104. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Ingesting Plaintiff and Ingesting Plaintiffs physicians the true and significant risks associated with Xarelto® use.

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

FACTUAL ALLEGATIONS

106. Prior to February 15, 2013, Ingesting Plaintiff was being treated for AFib and was reasonably well controlled on Coumadin/Warfarin insofar as he had not experienced any significant adverse events such as bleeding or a stroke.

107. Accordingly, prior to 2/15/2013, Ingesting Plaintiff had been successfully treated with Coumadin/Warfarin. Consistent with Defendants' representations and marketing discussed elsewhere herein, Ingesting Plaintiff's prescribing physician changed his prescription, at least in-part, to avoid the monitoring associated with Coumadin/Warfarin.

108. On or about 2/14/2013, Ingesting Plaintiff underwent a cardiac catheterization procedure. Following the procedure, Mr. Garza "did well from it" and was discharged home. In preparation for this procedure, Ingesting Plaintiff's treating physician ordered Mr. Garza removed from Coumadin/Warfarin and to start taking Xarelto, 20mg (daily) after the procedure.

109. On or about 2/15/2013, Ingesting Plaintiff was first prescribed and began taking Xarelto® upon direction of Ingesting Plaintiff's physician for AFib.

110. On or about 2/17/2015, Ingesting Plaintiff was home alone having a bowel movement, became dizzy, passed out, and was seriously injured in the fall on his head and left side. Ingesting Plaintiff was thereafter found unresponsive on the bathroom floor by Mrs. Garza when she arrived home.

111. When she found her husband, Mrs. Garza initially believed Mr. Garza had been shot. Mrs. Garza also observed bright red and dark tarry stool in the bathroom.

112. Mr. Garza sought medical attention with Mrs. Garza on or about 2/17/2013 and was transported by EMS to Christus Spohn Hospital where he was diagnosed, *inter alia,* with an un-coded lower GI bleed. As a direct result of Ingesting Plaintiff's ingestion of Xarelto®, Ingesting Plaintiff suffered acute GI bleeding, received multiple units of blood, and was admitted as an inpatient on 2/17/2013 to Christus Spohn in Alice, TX.

113. The bleeding event which Mr. Garza experienced after being switched to Xarelto® overloaded Mr. Garza sending him into respiratory failure and acute anemia due to GI bleed leading to several months of in-patient care at multiple health care facilities prior to his death on 5/19/2013 at the Corpus Christi Medical Center.

114. Nevertheless, Mr. Garza was discharged from Spohn Health on or about 2/25/2013 and transferred and admitted to Memorial Hermann in Houston, TX that same day. Mr. Garza remained a Memorial Hermann from 2/25/2013 until 4/10/2013.

115. At Memorial Hermann, Mr. Garza was originally scheduled for heart surgery. However, Mr. Garza's treatment quickly changed following the ingestion of Xarelto® to treatment for GI bleeding of unknown origin and a fall.

116. At Memorial Hermann, Mr. Garza's physicians were unable to wean him from a ventilator and he required multiple transfusions due to acute anemia. Further, Mr. Garza's physicians could not perform several procedures which would have helped Mr. Garza's treatment and recovery due to the injury he sustained to his kidney and acute GI bleeding following the ingestion of Xarelto®, a drug which overloaded Mr. Garza and placed his life in peril.

117. But for the ingestion of Xarelto®, Mr. Garza would have very likely received the care which was recommended by his treating physicians. Instead, Mr. Garza was thereafter discharged from Memorial Hermann to Kindred Hospital in Corpus Christi, TX on or about 4/10/2013 with recurrent GI bleeds.

118. Mr. Garza was then transferred to Kindred Hospital, n/k/a Post Acute Medical Specialty of Corpus Christi on 4/10/2013 until 4/15/2013. Mr. Garza was thereafter transferred to Corpus Christi Medical Center on 4/15/2013 for a lower GI bleed until 4/21/2013 when he was discharged from Corpus Christi Medical Center to Doctors Regional in order to attempt rehabilitation.

119. However, Mr. Garza was re-admitted to Corpus Christi Medical Center on or about 5/6/2013 until the time of his death on 5/19/2013. Upon information and belief, the causes of Mr. Garza's death were exacerbated, and triggered, by his use of Xarelto®.

120. As a direct result of being prescribed Xarelto® for this period of time, Ingesting Plaintiff has suffered significant injuries, including but not limited to wrongful death, such as those described above.

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

122. Ingesting Plaintiff would not have used Xarelto® had Defendants properly disclosed the risks associated with its use.

123. Ingesting Plaintiff's treating physician would not have prescribed Xarelto® had Defendants properly or reasonably disclosed the risks associated with its use.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATION

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

125. 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 Ingesting Plaintiff's physicians and/or Ingesting Plaintiff, 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.

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

127. Neither Ingesting Plaintiff, nor Ingesting Plaintiff's physicians, could not have reasonably, or possibly, determined the nature, extent and identity of related health risks associated with Xarelto®. Ingesting Plaintiff and Ingesting 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.

128. 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 non- public information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew this information was not available to the Ingesting Plaintiff or their physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

129. WHEREFORE, Ingesting Plaintiff prays for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiff for their injuries.

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN AND DESIGN DEFECT

130. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

131. At all times relevant and material hereto, Defendants were engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals, including the Xarelto at issue in this lawsuit, for the sale to, and use by, members of the public. The Xarelto® manufactured by Defendants reached Ingesting Plaintiff 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 Ingesting Plaintiff.

132. Defendants, as manufacturers and distributers of pharmaceutical 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.

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

134. Defendants had a continuing duty to provide consumers, including Ingesting Plaintiff, and Ingesting 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.

135. 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 Ingesting Plaintiff, 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 Ingesting Plaintiff.

136. 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.

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

138. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Ingesting Plaintiff and to Ingesting Plaintiffs 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 Ingesting Plaintiff and Ingesting Plaintiff'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;

d) 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, the use of Xarelto® by patients with AFib caused "by a heart valve problem."

139. Defendants had an obligation to provide Ingesting Plaintiff and Ingesting Plaintiff'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.

140. By failing to provide Ingesting Plaintiff and Ingesting Plaintiff'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.

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

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

143. As to Count I - Strict Products Liability, Ingesting Plaintiff reserves its rights to amend this cause of action, or seek a court order to apply any applicable law of the Ingesting Plaintiff's home state.

COUNT II: NEGLIGENCE

144. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

145. Defendants owed a duty to the general public, and specifically to the Plaintiffs, 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 Ingesting Plaintiff 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 Ingesting Plaintiff during foreseeable use.

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

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 Ingesting Plaintiff and Ingesting Plaintiffs physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Ingesting Plaintiff;

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 Ingesting Plaintiff, 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 Ingesting Plaintiff 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 Ingesting Plaintiff;

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 Ingesting Plaintiff's prescribing physicians, that this drug was safe and effective for use.

147. The Xarelto® that injured Plaintiffs was in substantially the same condition when Ingesting Plaintiff 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 Ingesting Plaintiff, was not due to any voluntary action or contributory negligence of Ingesting Plaintiff. Ingesting Plaintiff consumed the Xarelto® as directed and without change in its form or substance.

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

149. Plaintiffs seek all damages to which Plaintiffs may be justly entitled.

150. The Plaintiffs' injuries and damages are severe and permanent, and will continue into the future and were accompanied by fraud, malice, and/or gross negligence. As a result, the Plaintiffs seek actual and punitive damages from the Defendants as allowable by law.

151. As to Count II-Negligence, Plaintiffs reserve its rights to amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiff's home state.

COUNT III: NEGLIGENCE - FAILURE TO WARN

152. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

153. 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.

154. 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.

155. Ingesting Plaintiff was prescribed and used Xarelto® for its intended purpose.

156. Ingesting Plaintiff could not have known about the dangers and hazards presented by Xarelto®.

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

158. 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.

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

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

161. As a direct and proximate result of Xarelto's® defective and inappropriate warnings, Plaintiffs have suffered severe physical injuries and damages as described above and elsewhere herein.

162. As a direct and proximate result of the wrongful acts of the Defendants, Ingesting Plaintiff suffered severe and irreparable bodily injury and death; suffered great pain of body and mind; suffered great embarrassment and humiliation; incurred expenses for medical treatment of Ingesting Plaintiffs' injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

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

164. As to Count III-Negligence- Failure to Warn, Plaintiffs reserve their right to amend this cause of action or seek a court order to apply any applicable law of the Plaintiffs' home state.

COUNT IV: NEGLIGENCE - UNREASONABLE MARKETING OF A DANGEROUS DRUG AND UNREASONABLE FAILURE TO REMOVE THE DRUG FROM THE MARKET

165. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

166. Defendants owed a duty to the general public, and specifically to the Ingesting Plaintiff, 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 Ingesting Plaintiff during foreseeable use.

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

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.

168. The Xarelto® that injured Ingesting Plaintiff was in substantially the same condition when Ingesting Plaintiff 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 Ingesting Plaintiff was not due to any voluntary action or contributory negligence of Ingesting Plaintiff. Ingesting Plaintiff consumed the Xarelto® as directed and without change in its form or substance.

169. Defendants' violation of its duty of care resulted in an untenably dangerous product being placed into the marketplace which was a proximate cause of Ingesting Plaintiffs injuries and damages.

170. Plaintiffs seek all damages to which Plaintiffs may be justly entitled.

171. The Plaintiffs' injuries and damages are severe and permanent, will continue into the future, and were accompanied by circumstances of fraud, malice,

and/or gross negligence. As a result, the Plaintiffs seeks actual and punitive damages from the Defendants.

172. As to Count IV- Negligence, Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market, Plaintiffs reserves its rights to amend this cause of action or seek a court' order to apply any applicable law of the Plaintiffs' home state.

COUNT V: BREACH OF WARRANTY - BREACH OF EXPRESS WARRANTY

173. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

174. 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 Ingesting Plaintiff, or persons responsible for consumer.

175. 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 Ingesting Plaintiff 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 Ingesting Plaintiff concerning Xarelto® sold to Ingesting Plaintiff.

176. As a direct, foreseeable, and proximate result of Defendants' breaches of express warranties, Ingesting Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Ingesting Plaintiffs physician, in reasonable reliance upon such express warranties, prescribed for Ingesting Plaintiff the use of Xarelto®. Ingesting Plaintiff purchased and ingested Xarelto® as prescribed and instructed by Ingesting Plaintiff's physician, leading to Plaintiffs' injuries.

177. The Ingesting Plaintiff's injuries and damages are severe and permanent, will continue into the future, and were accompanied by circumstances of fraud, malice, and/or gross negligence. As a result, the Plaintiffs seek actual and punitive damages from the Defendants.

178. As to Count V- Breach of Warranty, Breach of Express Warranty, Plaintiffs reserve their right amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiffs home state.

COUNT VI: BREACH OF WARRANTY - BREACH OF IMPLIED WARRANTY

179. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

180. 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, health care professionals and consumers, including Ingesting Plaintiff, or persons responsible for consumer.

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

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

183. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Ingesting Plaintiff suffered grievous bodily injury and consequential economic and other losses, as described above, when Ingesting Plaintiff ingested Xarelto®, in reasonable reliance upon the implied warranties, leading to the Plaintiffs' injuries.

184. The Ingesting Plaintiff's injuries and damages are severe and permanent, will continue into the future, and were accompanied by circumstances of fraud, malice, and/or gross negligence. As a result, the Plaintiffs seek actual and punitive damages from the Defendants.

185. As to Count VI- Breach of Warranty, Breach of Implied Warranty, Plaintiffs reserve their right to amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiffs home state.

COUNT VII: FRAUDULENT CONCEALMENT

186. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

187. 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.

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

189. Despite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Ingesting Plaintiff and prescribing physicians, concerning the use and safety of Xarelto®.

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

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

192. 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.

193. The Defendants' statements and omissions were made with the intent that the Plaintiff, and Ingesting Plaintiff's prescribing physician, would rely on them.

194. The Ingesting 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.

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

196. Ingesting Plaintiff endured substantial pain and suffering, including death. As a result, the Plaintiffs have incurred significant expenses for medical care and will continue to be economically and emotionally harmed in the future.

197. The Ingesting Plaintiff's injuries and damages are severe and permanent, will continue into the future, and were accompanied by circumstances of fraud, malice, and/or gross negligence. As a result, the Plaintiffs seek actual and punitive damages from the Defendants.

198. As to Count VII-Fraudulent Concealment, Plaintiffs reserve their right to amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiff's home state.

COUNT VIII: VIOLATION OF CONSUMER PROTECTION LAWS

199. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

200. Ingesting 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.

201. 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.

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

203. 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 Ingesting Plaintiff in the marketing and advertising campaign described herein.

204. Defendants' conduct in connection with Xarelto® was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendant 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®.

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

206. As to Count VIII-Violation of Consumer Protection Law, Plaintiff reserve their right to amend this cause of action or seek a court order to apply any applicable law of the Plaintiffs' home state.

COUNT IX: LOSS OF CONSORTIUM

207. Plaintiffs incorporate by reference each and every paragraph of this complaint as if fully set forth herein.

208. At all relevant times, Israel Garza and Mary Lou Garza were husband and wife.

209. As more fully set forth previously herein, Defendants owed Ingesting Plaintiff a duty of care.

210. Defendants breached their duty of care to Ingesting Plaintiff.

211. As a direct and proximate result of Defendants' breach of their duty of care and negligence, Ingesting Plaintiff was injured and suffered death.

212. Before suffering these injuries, Israel Garza, as Mary Lou Garza's spouse, was able to perform all the duties of a spouse and did perform all these duties, including assisting in maintaining the family home, raising children, providing love, companionship, affection, and support to Plaintiff Mary Lou Garza.

213. Israel Garza can no longer perform the services of a spouse which thereby denies Plaintiff Mary Lou Garza of the care, companionship, affection, society, services, and of the emotional or intangible elements of the marital relationship of her spouse.

214. As a direct and proximate result of the Defendants' acts, the Plaintiff suffered irreparable injuries.

215. Plaintiff endured, and endures, substantial emotional pain and mental suffering. The Plaintiff has incurred significant expenses for medical care and will continue to be economically and emotionally harmed in the future. The Plaintiff's injuries and damages were caused by Defendants' fraud, malice, and/or gross negligence. As a result, the Plaintiff seeks actual, exemplary, and/or punitive damages from the Defendants to the fullest extent of the law.

216. As to Count IX-Loss of Consortium, Plaintiffs reserve their rights to amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiff's home state.

COUNT X: DAMAGES – COMPENSATORY AND PUNITIVE

217. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

218. Plaintiffs are entitled to punitive damages because Defendants' actions were caused by Defendants' fraud, malice, gross negligence reckless, and/or without regard for the public's safety. Defendants mislead both the medical community and the public at large, including Ingesting Plaintiff and Ingesting Plaintiff's physicians, by making knowingly 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 demonstration the product was unreasonably dangerous.

219. Defendants failed to provide warnings that would have dissuaded health care professionals from using Xarelto®, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using Xarelto®.

220. Defendants failed to provide adequate training and instructions to physicians to prevent Xarelto® from causing serious harm and suffering to patients, including Plaintiff.

221. As a proximate result of Defendants' acts and omissions, Plaintiffs suffered internal and gastrointestinal bleeding, and death, all resulting from Ingesting Plaintiff's ingestion of Xarelto®.

222. As a result of Ingesting Plaintiff's injuries, the Plaintiffs have endured substantial pain and suffering; has incurred significant expenses for medical care, burial, etc., and will remain economically challenged and emotionally harmed.

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

224. Defendants' actions were performed fraudulently, with malice and/or gross negligence, willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

225. Plaintiffs' injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiffs seek all actual, economic, noneconomic, exemplary, and punitive damages from the Defendants as permitted by law.

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

227. As to Count X- Damages, Compensatory and Punitive, Ingesting Plaintiff reserves its rights to amend this cause of action or seek a court order to apply any applicable law of the Ingesting Plaintiff's home state.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants as follows:

A. Awarding Plaintiffs' past and future medical and incidental expenses, according to proof;

B. Awarding Plaintiffs' past and future loss of earnings and/or earning capacity, according to proof;

C. Awarding Plaintiffs' past and future general damages, according to proof;

D. For compensatory damages according to proof, including pain, suffering and mental anguish;

E. Awarding punitive and exemplary damages in an amount to be determined at trial;

F. Awarding all economic and noneconomic, and exemplary damages allowable under Texas law in an amount to be proven at trial;

G. Awarding disbursements and expenses of this action, including reasonable attorney fees and other appropriate relief;

H. Awarding prejudgment and post judgment interest; and

I. Granting such other and further relief as is just and proper.

PLAINTIFFS REQUEST A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Respectfully Submitted,

Dated: May 19, 2015.

ELKUS SISSON & ROSENSTEIN, P.C.

/s/ Scott D. McLeod
Scott D. McLeod, Esq., CO # 38564
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Fax (303) 431-3753
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Attorneys for all Plaintiffs

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Mary Lou Garza, Individually and as Executrix of the ESTATE of ISRAEL M. GARZA, deceased

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Elkus Sisson & Rosenstein; Scott D. McLeod, Colorado #38564
501 S. Cherry Street, Suite 920
(303) 567-7981

DEFENDANTS

JANSSEN RESEARCH & DEVELOPMENT, LLC, et al.

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

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

Attorneys *(If Known)*

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

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal Injury, Product Liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 2,500,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Eldon E. Fallon, E.D. L.A. DOCKET NUMBER 14 MD 2592

DATE 05/19/2015

SIGNATURE OF ATTORNEY OF RECORD /s/ Scott D. McLeod

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

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

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

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

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

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