

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**IN RE: XARELTO (RIVAROXABAN) PRODUCTS
LIABILITY LITIGATION**

* **MDL NO. 2592**
* **SECTION L**
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* **JUDGE ELDON E. FALLON**
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* **MAG. JUDGE NORTH**
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**THIS DOCUMENT RELATES TO:
*ALL CASES***

ORDER AND REASONS

Before the Court are two Motions for Partial Summary Judgment filed by Defendants Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC, Johnson & Johnson, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc. (collectively, “Defendants”) arguing that Plaintiffs’ failure to warn claims are barred by the Learned Intermediary Doctrine. (R. Docs. 5118, 5119). Plaintiffs oppose these motions. Having considered the parties’ briefs and the applicable law and having heard the parties on oral argument, the Court now issues this order and reasons.

I. BACKGROUND

This matter arises from damages Plaintiffs claim to have suffered from the manufacture, sale, distribution, and/or use of the medication known as Xarelto, an anti-coagulant used for a variety of blood-thinning medical purposes. The Plaintiffs have filed suits against Defendants throughout the nation. The Plaintiffs allege that they or their family members suffered severe bleeding and other injuries due to Xarelto’s allegedly defective design and inadequate warning label, among other things.

The Judicial Panel on Multidistrict Litigation determined that the Plaintiffs' claims involved common questions of fact, and that centralization under 28 U.S.C. § 1407 would serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Therefore, on December 12, 2014, the Judicial Panel on Multidistrict Litigation consolidated the Plaintiffs' Xarelto claims into a single multidistrict proceeding ("MDL 2592"). MDL 2592 was assigned to Judge Eldon E. Fallon of the United States District Court for the Eastern District of Louisiana to coordinate discovery and other pretrial matters in the pending cases. Subsequent Xarelto cases filed in federal court have been transferred to this district court to become part of MDL 2592 as "tag along" cases. The Court has appointed committees to represent the parties, and discovery has commenced. The Court adopted a discovery plan and set bellwether trials to begin in April 2017. The first two trials involve Louisiana residents: Joseph Boudreaux and Sharyn Orr. The Defendants have filed a Motion in each case seeking summary judgment.

II. PRESENT MOTION

Defendants argue that the Learned Intermediary Doctrine bars the failure to warn claims proposed by both bellwether Plaintiffs: Boudreaux (R. Doc. 5118) and Orr (R. Doc. 5119). Specifically, Defendants argue that both Plaintiffs' prescribing physicians testified that an additional or different warning regarding Xarelto's risks would not have changed their decisions to prescribe Xarelto. Further, Defendants argue the label is legally adequate because it prominently warns of the risk of bleeding and the prescribing physicians testified that they were aware of that risk.

In their depositions, doctors for both Plaintiffs – Dr. St. James and Dr. Wong – testified that they stand by their decision to prescribe Xarelto. Accordingly, Defendants aver Plaintiffs cannot prove a failure to warn was the cause-in-fact or the proximate cause of their injuries. Both doctors knew there was no antidote for Xarelto and knew the risk of bleeding, yet still chose to

prescribe Xarelto. Further, while both doctors aver they would have used a test to monitor anticoagulation, they would only do so if it were FDA-approved. Defendants contend this test does not exist. In addition, the prescribing physicians testified that a PT test still may not have prevented the injury. Specifically, in the Boudreaux case, Defendants aver Plaintiff was administered a different PT test which showed him in the normal range. Accordingly, Defendants argue there is no causal connection between Plaintiffs' injuries and the failure to warn, and the arguments are barred by the learned intermediary doctrine.

Plaintiffs contend that Defendants miss the crux of the arguments: inadequate instruction. Defendants not only had a duty to warn about the risks of Xarelto, but also a duty to provide adequate instructions for its safe use. This duty extends to any healthcare provider in the position to make the use of the product safe. Plaintiffs contend that PT tests are required for safe use and that Defendants knew that PT tests were useful to evaluate Xarelto exposure.

Plaintiffs state that they do not argue that Defendants failed to warn of bleeding risk – that risk is obvious – but that Defendants did not adequately instruct doctors regarding available testing. Plaintiffs contend the label should have included instructions regarding Neoplastin PT tests and their use to help evaluate a patient's risk of bleeding on Xarelto and to assess a patient's exposure to Xarelto, for example, how much Xarelto is in a patient's system and whether or not a doctor should wait to perform emergency surgery. Plaintiffs contend Defendants failed to provide this information to doctors and further assert that Defendants had a duty not only to instruct prescribing physicians, but also Plaintiffs' other treating doctors.

Plaintiffs point to evidence that both doctors would have used PT tests had they been adequately instructed to do so, and therefore would have been equipped to adjust treatment to avoid injury. Specifically for Plaintiff Orr, Dr. Bui, her neurosurgeon, would have known Ms.

Orr was not anticoagulated and would have proceeded with her surgery much sooner. Because of the delay, however, Ms. Orr experienced significant medical issues.

III. LAW AND ANALYSIS

Summary judgment is appropriate when “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (citing FED. R. CIV. P. 56(c)); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). When assessing whether a dispute as to any material fact exists, the Court considers “all of the evidence in the record but refrains from making credibility determinations or weighing the evidence.” *Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co.*, 530 F.3d 395, 398 (5th Cir. 2008).

Under Federal Rule of Civil Procedure 56(c), the moving party bears the initial burden of “informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex*, 477 U.S. at 322. When the moving party has met its Rule 56(c) burden, “[t]he non-movant cannot avoid summary judgment . . . by merely making ‘conclusory allegations’ or ‘unsubstantiated assertions.’” *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002) (quoting *Little*, 37 F.3d at 1075). “The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986). All reasonable inferences are drawn in favor of the nonmoving party, but a party cannot defeat summary judgment with conclusory allegations or unsubstantiated assertions. *Little*, 37 F.3d at 1075. A court ultimately must be satisfied that “a reasonable jury could not return a verdict for the nonmoving party.” *Delta*, 530 F.3d at 399.

The applicable substantive law in these two cases is the Law of Louisiana. In cases involving prescription drug product liability, Louisiana applies the “learned intermediary doctrine” to failure-to-warn claims. *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002). Courts employ a two-pronged test when the learned intermediary doctrine is applicable: (1) the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that is not otherwise known to the physician, and (2) that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff’s injury. *Id.* at 265-66. “In order to demonstrate causation, ‘the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.’” *Eschete ex rel. Eschete v. Roy*, 554 F.Supp.2d 628, 633-34 (E.D. La. 2008) (quoting *Ferguson v. Proctor & Gamble Pharmaceuticals, Inc.*, 353 F.Supp.2d 674, 679 (E.D. La.2004)).

This Court finds that Plaintiffs do not contend that prescribing physicians never should have prescribed Xarelto. Instead, they argue their claim survives merely by showing the doctor would have acted differently had they been adequately instructed, and that Plaintiffs’ injuries could have then been avoided. Louisiana law contains a presumption that if adequate warning is provided, that warning would have been followed, or “heeded.” *See Bloxom v. Bloxom*, 512 So.2d 839, 850 (La. 1987); *ExxonMobil Wagoner v. Exxon Mobil Corp.*, 813 F.Supp.2d 771, 797 (E.D. La. Aug. 24, 2011). This presumption can be rebutted by showing that a warning would have been futile. In this case, the Court presumes that Plaintiffs’ doctors would have followed the label’s instructions and administered a PT test if so instructed, and Defendants fail to overcome that presumption at this juncture. Both doctors testified in their depositions that they

would have administered PT tests if the label so instructed. This issue, however, is factually pregnant and will be addressed by the jury at trial

This Court has reviewed the depositions of both Plaintiffs' prescribing Doctors – Dr. St. Martin and Dr. Wong – and finds that genuine issues of fact remain as to whether the doctors were adequately instructed and warned, and whether a different instruction or warning would have changed the doctors' actions and avoided or lessened Plaintiffs' injuries. For that reason, summary judgment is inappropriate at this time and the issue of whether the learned intermediary doctrine precludes Plaintiffs' recovery is left for the factfinder at trial.

IV. CONCLUSION

For the aforementioned reasons, Defendants' Motions for Partial Summary Judgment (R. Docs. 5118, 5119) are **DENIED**.

New Orleans, Louisiana, this 17th day of April, 2017.


UNITED STATES DISTRICT JUDGE