UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	*	**MDL NO. 2592**
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	*	**SECTION L**
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	*	**JUDGE ELDON E. FALLON**
	*	
	*	**MAG. JUDGE NORTH**
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THIS DOCUMENT RELATES TO:
Dora Mingo v. Janssen, et al. **(Rec. Doc. 6742)**

ORDER AND REASONS

Before the Court is Defendants' motion for partial summary judgment on Plaintiff's failure-to-warn claim. Defendants argue that Plaintiff's failure-to-warn claims are barred by the learned intermediary doctrine. Plaintiff opposes the motion. *Mingo* is the third bellwether trial in this multidistrict litigation series; Mississippi law applies here. The Court held oral arguments on this matter on June 21, 2017. Having considered the parties' arguments, submissions, and the applicable law, the Court now issues this Order and Reasons.

I. BACKGROUND

A. Xarelto MDL

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. Plaintiffs have filed suits against Defendants throughout the nation. 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 issues.

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 this Court 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, with assistance of counsel, identified a discovery pool of representative cases and selected four bellwether trials. This Order and Reasons relates to the third bellwether trial, involving Plaintiff Dora Mingo, a resident of Mississippi.

B. Ms. Mingo's Incident[1]

Plaintiff Dora Mingo underwent a right total hip replacement surgery on January 6, 2015. On January 22, 2015, she was diagnosed with a deep vein thrombosis ("DVT") in her right lower leg at Southwest Mississippi Regional Medical Center. She was admitted to the hospital under the care of Dr. Renie Jordon, who first evaluated Ms. Mingo on the morning of January 23, 2015, and prescribed Xarelto for her DVT, which developed while she was on Lovenox and then aspirin for anticoagulation after she underwent hip replacement surgery. *See* Def.'s Mot. (Rec. Doc. 6753) at 2. Dr. Jordon prescribed Xarelto 15 mg twice-daily for 21 days, then 20 mg once-daily thereafter. Prior to receiving her first dose of Xarelto on January 23, 2015, Ms. Mingo's PT was normal at 12.5 (reference range 12.1-15.2). After receiving her first and second dose of Xarelto,

[1] Unless otherwise indicated, the events occurred herein are described from Plaintiffs' brief. *See* Rec. Doc. 7038 at 3-4.

a PT test performed on January 24, 2015 revealed Ms. Mingo's PT was high at 23.6 (reference range 12.1-15.2).

When Ms. Mingo was discharged from the hospital on January 24, 2015, she was instructed to continue taking Xarelto. On February 12, 2015, bloodwork performed by Ms. Mingo's primary care physician, Dr. Jennifer Gholson, showed her hemoglobin was 5.8 (reference range: 12.0-16.0) and her hematocrit was 19.8 (reference range: 36-48). On the morning of February 13, 2015, Ms. Mingo had already taken her last scheduled dose of Xarelto 15 mg, when she received a call from Dr. Gholson's office, instructing her to go to the emergency room immediately.

Ms. Mingo went to the emergency room at Southwest Mississippi Regional Medical Center. Additional tests confirmed severe anemia and an acute upper GI bleed, with a PT measurement of 26.2. Ms. Mingo was admitted to the ICU for further treatment, and her Xarelto use was discontinued upon admission.

That same day, Ms. Mingo was transfused with four units of packed red blood cells and two units of fresh frozen plasma. Dr. Stephen Keith, a gastroenterologist, also performed an esophagogastroduodenoscopy (EGD), which revealed a 6mm oozing ulcer of the fundus. Dr. Keith ablated the bleeding ulcer with Argon Plasma Coagulation and placed a hemoclip for hemostasis. Ms. Mingo remained in the ICU for two more days, until February 15, 2015.

II. LEGAL STANDARDS

A. Summary Judgment

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.

B. Learned Intermediary Doctrine

When a plaintiff in Mississippi asserts a warning defect claim:

> (a) The manufacturer . . . of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller:
>
> (i) . . . The product was defective because it failed to contain adequate warnings or instructions, . . . ; and
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and

> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.
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> * * *
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> (c) (i) In any action alleging that a product is defective because it failed to contain adequate warnings or instructions . . . , the manufacturer . . . shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer . . . , the manufacturer . . . knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition.
>
> (ii) An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

Miss. Code Ann. § 11-1-63(a), (c) (2013).

As provided in Subsection (c)(ii), "[w]hen the product is a prescription drug, Mississippi follows the 'learned intermediary doctrine' which holds that the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary." *Deese v. Immunex Corp.*, 2012 WL 463722 (S.D. Miss. Feb. 13, 2012). Therefore, "the drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drugs," but the "duty to warn only extends to physicians and not to laymen." *Wyeth Labs., Inc. v. Fortenberry*, 530 So.2d 688, 691 (Miss. 1988).

III. PRESENT MOTION

Defendants argue that the learned intermediary doctrine bars the failure to warn claims proposed by Plaintiff. First, Defendants contend that Xarelto's warning language in January 2015 was adequate because it warned of the risk of major bleeding, and Dr. Jordon was fully aware of risks associated with taking Xarelto. Rec. Doc. 6742 at 6. Defendants highlight that the label blatantly warned of the exact risk Ms. Mingo experienced: bleeding. *Id.* It stated, among other things, that "XARELTO increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe XARELTO to patients at increased risk of bleeding, the risk of thrombotic events should be weighed against the risk of bleeding." *Id.* Accordingly, Defendants conclude that the warnings on Xarelto were adequate and sufficient to inform Plaintiff's prescribing physician if the risks associated with using Xarelto. *Id.* at 7.

Second, Defendants emphasize that Dr. Jordon suggested in his deposition that an additional or different warning regarding Xarelto's risks would not have changed his decision to prescribe Xarelto. *Id.* at 8. Defendants argue that Dr. Jordon fully understood the risks and benefits from using Xarelto, and still decided to prescribe Xarelto. *Id.* In fact, Dr. Jordon continues to prescribe Xarelto to other patients today. *See id.*

In response, Plaintiff clarifies that Ms. Mingo does not allege that Defendants failed to warn of Xarelto's bleeding risk. Rec. Doc. 7038 at 11. Rather, Ms. Mingo claims that Defendants failed to instruct physicians regarding the need and ability to evaluate Xarelto's anticoagulant effect on individual patients with standard laboratory testing. *Id.* at 11-12. Specifically, Plaintiff alleges that Defendants failed to adequately instruct physicians about Xarelto's clinically significant inter-patient variability, meaning that certain Xarelto-treated patients will have a higher bleeding risk, and that standard laboratory testing, including a Neoplastin PT test, can be used to identify patients at higher risk for bleeding. Consequently, Plaintiff argues that Defendants failed

to adequately instruct physicians, including Dr. Jordon, regarding the need and ability to use standard laboratory testing for evaluating a patient's exposure and risk of bleeding on Xarelto. *See generally id.* Plaintiff points to Dr. Jordon's deposition to show that if he would have known of a test to evaluate the effect Xarelto was having on Ms. Mingo, he would have utilized the test and changed her dosage or medication accordingly. *Id.* at 22.

IV. DISCUSSION

This Court finds that genuine issues of material fact remain as to whether (1) the warning or instruction was adequate; and (2) if not, would an adequate warning or instruction have changed the prescribing physician's conduct. Plaintiff does not contend that prescribing physicians should have never prescribed Xarelto. Instead, Plaintiff argues that her doctor would have acted differently had he been adequately instructed—whether changing the dosage or shortening the prescription period. Thus, Plaintiff argues that her injuries could have then been avoided or diminished.

Defendants attempt to distinguish the learned intermediary doctrine in the instant case from the Court's holding in *Boudreaux* and *Orr*. *See In re: Xarelto (Rivaroxaban) Products Liability Litigation*, 2017 WL 1393480, at *3 (E.D. La. 2017). They have, however, failed to do so. The Court is cognizant that *Mingo* is in a different jurisdiction and with different case law. But the analysis does not change. First, the Mississippi Products Liability Act codifies the learned intermediary doctrine and defines "[a]n adequate product warning *or instruction* is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and *safe use of the product* . . . ." Miss. Code Ann. § 11-1-63(c)(ii) (emphasis added). Although Defendants have emphasized—"Xarelto package mentioned 'bleed' or 'bleeding' more than 100 times"—that their

warnings are adequate as a matter of law, a reasonable fact finder could nonetheless conclude that quantity does not mean quality.

Second, Defendants argue that under Mississippi law, "the Court must focus only on the drug label's effect on the physician's *prescribing decision*. . . ." Rec. Doc. 6742 at 10 (citing *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (emphasis original). In *Thomas*, the plaintiff began the acne treatment Accutane, and thereafter suffered disorientation, headaches, and eventually seizures. *Id.* at 808. At trial, she presented evidence that the warning given to prescribing physicians about Accutane was inadequate. *Id.* at 809-10. The district court set aside a verdict in her favor, and on appeal Thomas argued that Mississippi law did not require that the plaintiff show that an adequate warning would have changed the prescribing physician's action. *Id.* at 811-13. The Fifth Circuit rejected that argument, holding that under Mississippi law, "the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff." *Id.* at 812.

Thomas can be distinguished. The Fifth Circuit's analysis there focused on whether the defendant adequately warned of dangers and side effects associated with prescribing the drug—not *instructions* for safe use of the drug. *See id.* at 814-815, 817. It is undisputed that Xarelto, as well as other anticoagulants, carry the risk of bleeding. The question in the instant case, and Plaintiff's argument here, is not whether Dr. Jordon would still have prescribed Xarelto, but rather whether he would have prescribed it differently if those instructions were given. Therefore, a physician's "prescribing decision" is not simply limited to "either-or" but also includes "how" and "how much." In Mississippi, product liability extends to defects in warnings, as well as "instructions." Miss. Code Ann. § 11-1-63(c)(ii).

Here, Dr. Jordon testified that if he would have known of a test to evaluate the effect Xarelto was having on Ms. Mingo, he would have utilized the test and changed her dosage or medication accordingly. *See* Rec. Doc. 7038 at 22. Additionally, Plaintiff has proffered objective evidence of how a reasonable physician would have considered and responded if Defendants had provided adequate instructions on the use of PT in Xarelto's label. Plaintiff expert Dr. Henry Rinder explained in his report that if "Ms. Mingo's treating physicians been informed of the general linear correlation between PT measurements and Xarelto concentrations, and the correlation of PT with risk of bleeding on Xarelto . . . , Ms. Mingo's excessive exposure and unnecessary high risk of bleeding would have been identified at the onset of her treatment." *See id.* at 23. Thus, the Court finds that Plaintiff could satisfy the learned intermediary doctrine at trial.

Accordingly, summary judgment is inappropriate at this juncture. *See Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 59 (Miss. 2004) (Mississippi Supreme Court affirmatively noting "issue of whether the FDA-approved labeling was adequate . . . should be determined by the jury.").

V. CONCLUSION

Based on the aforementioned reasons, Defendants' motion for partial summary judgment based on the learned intermediary doctrine (Rec. Doc. 6742) is hereby **DENIED**.

New Orleans, Louisiana, this 24th day of July, 2017.

ELDON E. FALLON
United States District Judge