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. Docs. 6745 & 6749)**

ORDER AND REASONS

Before the Court are 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 federal law preempts Plaintiff's failure-to-warn claim and design-defect claim under the Mississippi Products Liability Act ("MPLA"). Plaintiff opposes the motions. 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. The instant case is the third bellwether trial involving Plaintiff Dora Mingo, a resident of Mississippi

B. Ms. Mingo's Incident[1]

Plaintiff 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 labeled under Rec. Doc. 7006-2.

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. The Supremacy Clause and Preemption

"The Supremacy Clause of the Constitution prohibits state laws from conflicting with federal law." *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 928-29 (5th. Cir. 2006) (citing U.S. CONST. art. VI, cl. 2). Therefore, "[a] 'state law that conflicts with federal law'" is

federally preempted and "'without effect.'" *Id.* at 929 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

Inevitably, "'[t]he purpose of Congress is the ultimate touchstone' in every preemption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 106 (1963)). Congressional intent is primarily "discerned from the language of the preemption statute and the 'statutory framework' surrounding it." *Id.* at 486 (quoting *Gade*, 505 U.S. at 111, 112). However, the Court should also review the "'structure and purpose of the statute as a whole'" in order to determine "the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* (quoting *Gade*, 505 U.S. at 98). Furthermore, "[i]n all preemption cases, and particularly in those in which Congress has 'legislated . . . in a field in which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 485 (citation omitted); *see also Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

III. PRESENT MOTIONS

A. Failure-to-Warn Claim

Defendants proffer four reasons for summary judgment on the failure-to-warn claim based on "impossibility" preemption principles. First, Defendants state they could not independently or unilaterally change Xarelto's label to instruct doctors to conduct PT testing because (1) Defendants could not recommend in Xarelto's label an off-label use of Neoplastin—which was designed (and cleared by FDA) explicitly for use with warfarin, not Xarelto, and must receive a separate "safety and efficacy" clearance for use with companion therapeutic products such as Xarelto; and (2) Plaintiffs' proposed Neoplastin-related instruction is a "monitoring recommendation" that cannot be added to the Xarelto label without prior FDA approval,

pursuant to FDA regulations and guidances. Rec. Doc. 6749 at 3. Second, Defendants contend there is "clear evidence" that FDA would have rejected Plaintiffs' proposed instruction regarding PT: prior to Xarelto's approval, Janssen specifically proposed the very PT-related language that Plaintiff say Xarelto's labeling should have included, but FDA struck that language. *Id.* Third, Defendants aver that Janssen could not have independently added PT information to Xarelto's labeling because there was no "newly acquired information" that would justify a change under the CBE procedure. *Id.* at 4. Finally, Defendants argue that any claim for a "black box" warning is also preempted because a pharmaceutical company cannot unilaterally add a black-box warning to a label. *Id.*

B. Design-Defect Claim

Defendants also argue that federal law preempts Plaintiff's design-defect claims because those claims would require Defendants to take actions that they cannot lawfully take "independently." Defendants contend that federal law preempts Plaintiff's claim that Xarelto is unreasonably dangerous because the medicine's FDA-approved dosages are too high or should be reduced. Rec. Doc. 6745 at 9. Defendants allege that Plaintiff's dosing-related claims challenge the FDA-approved design of Xarelto and are preempted by federal law, which strictly forbids Defendants to change Xarelto's design—including by altering or adjusting approved dosages—without FDA's prior authorization. And because Defendants cannot independently change Xarelto's FDA-approved dosage, Defendants argue that Plaintiff's dosing and monitoring-related theories are preempted. Moreover, Defendants argue that the anti-Factor Xa assay is an altogether separate product, and FDA has not yet cleared any anti-Factor Xa assay for any purpose. Defendants ground their reasoning based on, *inter alia*, the Supreme Court's decision in *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013); Sixth Circuit's holding in

Yates v. Ortho-McNeil-Janssen, 808 F.3d 281 (6th Cir. 2015); and Southern District of New York's opinion in *Utts v. Bristol-Myers Squibb Co.*, *Utts v. Bristol-Myers Squibb Co.*, __ F. Supp. 3d __, MDL No. 2754, 2017 WL 1906875 (S.D.N.Y. May 8, 2017). Under similar theory for preemption on the dosing claim, Defendants argue that federal law preempts Plaintiff's claim that Xarelto is unreasonably dangerous because it does not entail a requirement or recommendation that doctors monitor their patients' Xarelto-related coagulation parameters. Defendants contend that Plaintiff's monitoring-related theories are preempted because Defendants cannot "independently" alter Xarelto's design to incorporate PT monitoring, as no PT test or assay has been cleared or approved for use in conjunction with Xarelto and any such use would require prior FDA authorization. Rec. Doc. 6745 at 22. Defendants further argue that federal law preempts Plaintiff's claim that Xarelto is unreasonably dangerous in the absence of a Xarelto-specific anti-Factor Xa assay, *see id.* at 23, as well as unreasonably dangerous in the absence of a reversal agent. *See id.* at 24.

IV. DISCUSSION

This Court is well aware of the divide among federal and state courts on the issue of FDA preemption. Nonetheless, consistent with *Boutreaux* and *Orr*, this Court refuses to stretch the preemption doctrine beyond its existing borders. *See generally In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. MDL 2592, 2017 WL 1395312 (E.D. La. Apr. 13, 2017); *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. MDL 2592, 2017 WL 1393508, at *1 (E.D. La. Apr. 13, 2017). Doing so would free pharmaceutical companies from state common-law liability—and limit states' constitutional right to protect its residents' welfare—so long as manufacturers are selling a federally-approved drug. "Congress did not provide a federal remedy for consumers

harmed by unsafe or ineffective drugs . . . . Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." *Levine*, 555 U.S. at 555.

The United States Supreme Court in *Wyeth v. Levine* provides a detailed explanation of Congress's purpose in enacting the Federal Drug and Cosmetics Act ("FDCA") and in legislating around the FDA's powers. *See id.* The Supreme Court found, among other things, that Congress, throughout its legislative history, has "[taken] care to preserve state law," has declined to enact a preemption provision for prescription drugs, and "may have also recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Levine*, 555 U.S. at 567, 573-74. Simply put, Congress has demonstrated a clear intent to preserve the functions of both the FDA and state tort remedies. This Court intends to protect that balance.

Defendants argue that Plaintiff's claims are preempted because it would be impossible for them to simultaneously comply with both federal and state law. According to Defendants, for them to comply with Plaintiff's alleged requirements under the MPLA, Defendants would be required to take corrective action they cannot lawfully take unilaterally or independently. Under applicable FDA regulations and Supreme Court precedent, Defendants argue that they cannot unilaterally or independently alter an FDA-approved design without the FDA's prior approval. *Bartlett*, 133 S. Ct. at 2470-71. "Even in the absence of an express preemption provision, the Court has found state law to be impliedly preempted where it is "impossible for a private party to comply with both state and federal requirements." *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990); *see also Bartlett*, 133 S. Ct. at 2473.

But "[i]mpossibility preemption is a *demanding* defense." *Levine*, 555 U.S. at 573 (emphasis added). While this Court acknowledges that pharmaceutical companies generally

cannot take unilateral action or alter an FDA-approved drug, Defendants' argument take the preemption doctrine one step too far. Defendants rely on *Bartlett* and *Mensing*, both of which relate to generic drug manufacturers which are more limited in their ability to make changes to their labels than are manufacturers of name-brand drugs such as Xarelto. *See Bartlett*, 133 S. Ct. at 2466 (holding state law design defect claims for generic drugs that rely on the adequacy of a drug's warning are preempted under federal law); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (finding failure-to-warn claims preempted because federal law prevents generic drug manufacturers from changing their labels).

The preemption of claims against brand-name drug manufacturers is not as clear; neither Congress nor the Supreme Court has spoken directly on that issue. And until Congress or the Supreme Court does so, this Court is restrained to existing precedent. The *Levine* Court held that a state failure to warn claim against a brand-name drug manufacturer was not pre-empted by federal law, finding that Congress had clearly intended the judicial branch to work in concert with the FDA to protect against unnecessary risk. *See generally Levine*, 555 U.S. 555.

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id. at 578-79.

Alternatively, Defendants could have strengthened their label post-approval. Manufacturers remain the master of their labels even after FDA approval, and there are clear pathways through which a brand-name drug manufacturer can make changes to their label without FDA approval. "Among other things . . . 'changes being effected' (CBE) regulation provides that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval." *Levine*, 555 U.S. at 568 (citing §§ 314.70(c)(6)(iii)(A), (C)).

The Defendants point out that the manufacturer's ability to change a label under the CBE is limited to newly-acquired information. Both the FDA and the courts have clarified, however, that newly-acquired information is not limited to brand new information—it also includes "new analyses of previously submitted data." *Id.* at 569 (citing to 73 Fed. Reg. 49604). In this case, the Defendants may have been permitted to update their label pursuant to the CBE after they became aware of the number of its consumers claiming they experienced a major bleeding event while taking Xarelto. In any event, there are sufficient questions of fact to merit a jury determination of the issue.

Defendants contend the FDA's refusal to add Defendants' proposed subgroup information and their reaffirmation of the label after a post-approval review of the INRatio recall indicates as "clear evidence" that the FDA also would have refused to approve a similar label change under the CBE. The Court does not find this altogether clear. Plaintiffs argue that, with regards to the INRatio recall, after the post-approval review, the FDA invited comment regarding adding this information to the label, but Defendants did not respond. In their review, the FDA

recommended against a label change because they thought it would be hard to write clearly and concisely. Plaintiffs contend this is not clear evidence that a proposed change would be rejected. Further, they contend a label change is not the only way to warn doctors; they could have also warned doctors through medical publications, "Dear Doctor" letters, or advertisements. Regarding subgroup data, Plaintiffs contend that, while the FDA rejected North American data in the original label, they did not reject U.S.-specific data. Further, Plaintiff claims Defendants should have added the information through CBE after post-market studies showed a significant increase in bleeding events in the United States. Defendants did not push the FDA on the issue, and the FDA later added the information sua sponte.

The requirement, as elucidated by *Levine*, is "clear evidence" that the FDA would not approve the change. As this Court has previously noted in *Boudreaux* and *Orr*, clear evidence requires more than a prior refusal to add similar language. In *Levine*, the Defendant submitted a proposed warning to FDA. Although the FDA did not respond to the proposal, it later approved the Defendants' application without the proposed warning. Nevertheless, the Court found this insufficient, because there was no indication that the Defendant had "'earnestly attempted' to strengthen the . . . warning or that the FDA had 'specifically disallowed' stronger language." *Levine*, 555 U.S. at 561. Courts have found that the FDA and defendants are required to give more than "passing attention" to the issue: there must be evidence the FDA intended to or would *prohibit* a defendant from strengthening warning. *Id.* at 572. Defendants bear the responsibility for their label and may have been able to include U.S.-specific data at the outset or after post-market data was released showing high instances of bleeding. Further, issues of fact remain as to whether the Defendants could have warned doctors about the INRatio recall, either though the label or through other means. Finally, issues of fact remain as to whether Defendants could have

added a warning about the test's availability either pre-market or through CBE. The Court finds these issues in the instant case are factually pregnant and inappropriate for summary judgment.

Moreover, the court in *Guidry*, relying on *Levine*, found that Plaintiff's pre-market defective design claims under the Louisiana Products Liability Act were not preempted. *Guidry v. Janssen Pharms., Inc.*, No. 15-4591, 2016 U.S. Dist. LEXIS 115447, at *48 (E.D. La. Aug. 29, 2016). The *Guidry* court reasoned:

> Here, the plaintiff states in her complaint that the defendants knew Invokana's design posed an unreasonably dangerous risk of kidney injury before it was approved by the FDA, yet they sought FDA approval nonetheless. Louisiana law imposes a duty on all manufacturers to consider feasible, alternative designs and reasonably weigh the risks and utility of the final product before it leaves the manufacturer's control. Federal law does not prevent a drug manufacturer from complying with this state-imposed duty before seeking FDA approval. Far from impossible, the two are complimentary, preferable, and perhaps necessary to protect the public health and assure the safety, effectiveness, and reliability of drugs.

Id. This is exactly the Plaintiff's contention in the instant case. Plaintiff avers that Defendants should have designed a specific assay and/or an antidote before sending Xarelto to the FDA for approval. In the alternative, Defendants should have included a warning and instruction regarding the availability of Neoplastin PT tests to measure anticoagulation. Accordingly, much to Defendants' chagrin, *Guidry* is directly on point and the Court finds Plaintiffs' pre-market design-defect claims under the MPLA are not preempted.

Finally, and very importantly, at the core of preemption analysis is congressional intent. In *Levine*, the Supreme Court determined that Congress had declined to limit the historical state police power over health and safety matters and had allowed for coexistence between state and federal regulation of prescription medications. The Court took note that in contrast to the express preemption clause found in the Medical Device Amendment Act within the FDCA, no

such clause exists for branded prescription drugs. *See Levine*, 555 U.S. at 574. "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . . , Congress has not enacted such a provision for prescription drugs." *Id.* (citations omitted). Whether Congress decides to do so is their prerogative. This Court will not step inside Congress's shoes.

V. CONCLUSION

Based on the foregoing reasons, Defendants' motions for partial summary judgment based on preemption principles (Rec. Docs. 6745 & 6749) are **DENIED**.

New Orleans, Louisiana, this 21st day of July, 2017.

ELDON E. FALLON
United States District Judge