UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	*	**MDL NO. 2592**
	*	**SECTION L**
	*	
	*	**JUDGE ELDON E. FALLON**
	*	
	*	**MAG. JUDGE NORTH**
**********	*	

THIS DOCUMENT RELATES TO:
ALL CASES

ORDER AND REASONS

Before the Court is a Motion 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 Plaintiffs' dosing, monitoring, and other design-related claims. (R. Doc. 5109). Plaintiffs oppose the motion. 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.

II. PRESENT MOTION

Plaintiffs bring their claims in the first two bellwether trials under the Louisiana Products Liability Act (the "LPLA"). Specifically to this motion, they claim Xarelto was unreasonably dangerous because it was defectively designed. Defendants filed this motion for partial summary judgment, arguing that Plaintiffs' defective design claims are preempted by federal law. The two parties frame Plaintiffs' claims slightly differently. It is the Court's understanding that Plaintiff's design defect claim is as follows.

Xarelto markets itself as a one-size-fits-all anticoagulant. Patients take one 20-milligram dose of Xarelto once a day[1] and do not need to undergo routine monitoring. Plaintiffs contend that, because each person processes and metabolizes Xarelto at a highly-individualized rate, each patient's reaction to the drug is decidedly variable, causing some patients to experience major

[1] Patients may be prescribed a 15-milligram dose of Xarelto if they have renal problems.

bleeding events. Plaintiffs acknowledge that the Food and Drug Administration (the "FDA") approved Xarelto's dosing and monitoring scheme. However, they claim that, given the high inter-patient variability, Xarelto is unreasonably dangerous in design because (1) Defendants should have designed, but failed to design, a Xarelto-specific Anti-Factor Xa assay so doctors could monitor Xarelto's anticoagulation effect on each patient and could, along with the patient, weigh the risks and determine whether to continue taking Xarelto; (2) because Defendants have not designed and marketed an antidote to counteract a major bleeding event; and (3) in the absence of a Xarelto-specific Anti-Factor Xa assay, Xarelto's label should have warned doctors about the availability of the Neoplastin PT test to measure patient's anticoagulation. Because Defendants did not take any of the above three actions, Plaintiffs claim Xarelto is unreasonably dangerous under the LPLA.

III. APPLICABLE LAW

A. 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 pre-emption 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 pre-emption 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 pre-emption 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).

The Supreme Court in *Wyeth v. Levine* provides a detailed explanation of Congress' purpose in enacting the Federal Drug and Cosmetics Act (the "FDCA") and in legislating around the FDA's powers. *See generally Levine*, 555 U.S. 555. The 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. In short, Congress has demonstrated a clear intent to preserve the functions of both the FDA and state tort remedies.

B. Claims under the Louisiana Products Liability Act

A product can be "unreasonably dangerous" (i) in construction or composition; (ii) in design; (iii) for failure to provide an adequate warning; and (iv) for failure to conform to an express warranty. La. Rev. Stat. § 9:2800.54 et seq. To assert a design defect claim under the LPLA, a plaintiff must establish that, at the time the product left the manufacturer's control, (1) "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage" and (2) that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design." La. R.S. § 9:2800.56. *See Roman v. W. Mfg.*

Inc., 691 F.3d 686, 700-01 (5th Cir. 2012); *Jacobsen v. Wyeth, LLC*, No. 10-823, 2012 U.S. Dist. LEXIS 116887, at *6 (E.D. La. Aug.20, 2012). To prevail on a defective design claim, Plaintiff must also demonstrate, "that the danger of the damage outweighed the burden on the manufacturer of developing the alternative design." La. R.S. § 9:2800.56. This is sometimes referred to as the risk-utility test.

IV. ANALYSIS

Defendants argue that Plaintiffs' 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 Plaintiffs' alleged requirements under the LPLA, Defendants would be required to take corrective action they cannot lawfully take unilaterally or independently. Under applicable FDA regulations and Supreme Court precedent, they argue, they cannot unilaterally or independently alter an FDA-approved design without the FDA's prior approval. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013). "Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted 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 Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

"Impossibility pre-emption is a demanding defense." *Levine*, 555 U.S. at 573. While this Court acknowledges that pharmaceutical companies generally cannot take unilateral action or alter an FDA-approved drug, Defendants are stretching the law beyond its current bounds. Defendants rely on *Bartlett* and *Mensing*, both of which relate to generic drug manufacturers who are more limited in their ability to make changes to their labels than are manufacturers of name-brand drugs such as Xarelto. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (holding state law design defect claims for generic drugs that rely on the adequacy of a drug's warning are pre-empted under federal law); *PLIVA, Inc. v. Mensing*, 564 U.S. [_] (2011)

(finding failure to warn claims pre-empted because federal law prevents generic drug manufacturers from changing their labels).

The pre-emption of claims against brand-name drug manufacturers is not as clear. The Court in *Levine* 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 Wyeth v. Levine*, 555 U.S. 555 (2009).

> 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.

The court in *Guidry*, relying on *Wyeth*, found that Plaintiff's pre-market defective design claims under the LPLA 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) ("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."). This is exactly the Plaintiffs' contention in the instant case. Plaintiffs aver that Defendants should have designed an specific assay and/or and 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, *Guidry* is directly on point and the Court finds Plaintiffs' pre-market design defect claims under the LPLA are not preempted.

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." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009)(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.

While Defendants contend the FDA's refusal to add Defendants' proposed warning language indicates they would also refuse to approve a similar label change under the CBE, the Court does not find this altogether clear. The requirement, as elucidated by *Wyeth*, is "clear evidence" that the FDA would not approve the change. Clear evidence requires more than a prior refusal to add similar language. In *Wyeth*, the Defendant submitted a proposed warning to FDA which did not respond to the proposal, but 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." *Wyeth*, 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. The Court finds these issues in the instant case are factually pregnant and inappropriate for summary judgment.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion for Partial Summary Judgment (R. Doc. 5109) is **DENIED**.

New Orleans, Louisiana, this 12th day of April, 2017.

UNITED STATES DISTRICT JUDGE

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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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.

II. PRESENT MOTION

Plaintiffs bring their claims in the first two bellwether trials under the Louisiana Products Liability Act (the "LPLA"). Specifically to this motion, they claim Xarelto was unreasonably dangerous because of Defendants' failure to warn. La. Rev. Stat. § 9:2800.57. Plaintiffs contend that Xarelto's label should have instructed physicians that Neoplastin PT tests can be used to identify plaintiffs with high risk of bleeding, to inform treaters that the INRatio device used in the ROCKET AF trial was recalled, and to advise prescribing doctors about U.S.-specific bleeding risk. Under *Wyeth*, Plaintiffs aver, drug companies have the responsibility to draft adequate warnings – not the Food and Drug Administration ("FDA") – and they are responsible for updating them as new evidence comes to light. Further, Plaintiffs claim that Defendants failed to provide sufficient evidence that the FDA would have rejected a label change. To prove that the FDA would reject a label update, Defendants must press their position with the FDA; it is not enough that the FDA believed the label change was false or misleading or that the change

was not necessary. There must be clear evidence that the FDA would rescind Defendants' change to the label. Plaintiffs aver there is no such evidence of this.

Defendants seek partial summary judgment on Plaintiffs' failure to warn claims, arguing they are preempted because they are based on the same information that the FDA considered, thoroughly vetted and analyzed, and rejected for inclusion in Xarelto's label. Defendants argue the claims are preempted because they would require Defendants to take improper unilateral or independent action and because there is clear evidence that the FDA would have rejected (and did reject) the labeling changes Plaintiffs propose.

III. APPLICABLE LAW

A. The Supremacy Clause and Pre-emption

"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 pre-emption 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 pre-emption 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 pre-emption 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).

The Supreme Court in *Wyeth v. Levine* provides a detailed explanation of Congress' purpose in enacting the Federal Drug and Cosmetics Act (the "FDCA") and in legislating around the FDA's powers. *See generally Levine*, 555 U.S. 555. The 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. In short, Congress has demonstrated a clear intent to preserve the functions of both the FDA and state tort remedies.

B. Claims under the Louisiana Products Liability Act

A product can be "unreasonably dangerous" (i) in construction or composition; (ii) in design; (iii) for failure to provide an adequate warning; and (iv) for failure to conform to an express warranty. La. Rev. Stat. § 9:2800.54 et seq. To assert a failure to warn claim under the LPLA, a plaintiff must establish that, "at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." La. Rev. Stat. § 9:2800.57.

IV. ANALYSIS

Defendants argue that Plaintiffs' 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 Plaintiffs' alleged requirements under the LPLA, Defendants would be

required to take corrective action they cannot lawfully take unilaterally or independently. Under applicable FDA regulations and Supreme Court precedent, they argue, they cannot unilaterally or independently alter an FDA-approved design without the FDA's prior approval. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013). "Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted 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 Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

"Impossibility pre-emption is a demanding defense." *Levine*, 555 U.S. at 573. While this Court acknowledges that pharmaceutical companies generally cannot take unilateral action or alter an FDA-approved drug, Defendants are stretching the law beyond its current bounds. Defendants rely on *Bartlett* and *Mensing*, both of which relate to generic drug manufacturers who are more limited in their ability to make changes to their labels than are manufacturers of name-brand drugs such as Xarelto. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (holding state law design defect claims for generic drugs that rely on the adequacy of a drug's warning are pre-empted under federal law); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (finding failure to warn claims pre-empted because federal law prevents generic drug manufacturers from changing their labels).

The pre-emption of claims against brand-name drug manufacturers is not as clear. The Court in *Levine* 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 Wyeth v. Levine*, 555 U.S. 555 (2009).

> 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." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (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 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, Plaintiffs claim 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*.

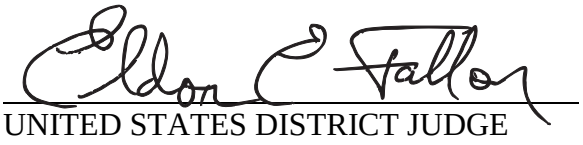
The requirement, as elucidated by *Wyeth*, is "clear evidence" that the FDA would not approve the change. Clear evidence requires more than a prior refusal to add similar language. In *Wyeth*, the Defendant submitted a proposed warning to FDA. Although the FDA did not respond to the proposal, it later 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." *Wyeth*, 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, while Defendants did not address the Plaintiffs' failure to warn claim regarding Neoplastin PT tests, as addressed in its order on design-defect preemption, 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.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion for Partial Summary Judgment (R. Doc. 5110) is **DENIED**.

New Orleans, Louisiana, this 13th day of April, 2017.



UNITED STATES DISTRICT JUDGE