UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	*	MDL 2592
	*	SECTION L
THIS DOCUMENT RELATES TO: Dora Mingo v. Janssen Research & Development, LLC, *et al.* Case No. 2:15-cv-03469	*	JUDGE ELDON E. FALLON
	*	MAGISTRATE JUDGE NORTH

* *

PLAINTIFF'S MEMORANDUM IN SUPPORT OF RULE 59 MOTION FOR A NEW TRIAL

I. INTRODUCTION

Plaintiff Dora Mingo requests a new trial because a striking new study and medical article conducted and co-authored by leading Bayer scientists was released as the trial was almost concluded, confirming Plaintiff's claims about the usefulness of PT Neoplastin. This study and article constitutes material new evidence that could not have been discovered by Plaintiff before trial and would have probably resulted in a different outcome at trial. This evidence renders key testimony of the Defendants' expert witnesses as misleading to the jury and supports Plaintiff's position on this critical issue.

Additionally, Plaintiff requests a new trial because of several errors addressing evidentiary rulings and instructions to the jury occurred which were so prejudicial to her trial that relief is warranted. Prejudicial evidence was admitted, and jury instructions important to Plaintiff's case were mishandled or rejected. The evidentiary errors along with the new evidence, considered either individually or cumulatively, affected Plaintiff's substantial rights, and, accordingly, Ms. Mingo is entitled to a new trial.

II. LEGAL STANDARD

After a jury trial, a district court may grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). "Although Rule 59(a) does not list specific grounds for a new trial, the United States Court of Appeals for the Fifth Circuit has held that a new trial may be granted if 'the verdict is against the weight of the evidence, the damages awarded are excessive, the trial was unfair, or prejudicial error was committed in its course.'" *In re Vioxx Prods. Liab. Litig.*, 489 F. Supp. 2d 587, 589 (E.D. La. 2007), *citing Smith v. Transworld Drilling Co.*, 773 F.2d 610, 613 (5th Cir. 1985). A district court also has discretion to grant a new trial on the basis of newly discovered evidence. *Randle v. Tregre*, No. CV 15-395, 2016 WL 760770, at *2 (E.D. La. Feb. 26, 2016) (citing *Diaz v. Methodist Hosp.*, 46 F.3d 492, 495 (5th Cir. 1995)). *See also Songcharoen v. Plastic & Hand Surgery Assocs., PLLC*, No. 3:11-CV-308-WHB-LRA, 2013 WL 12123524, at *3 (S.D. Miss. Apr. 11, 2013) ("Grounds for granting a new trial include: *** newly discovered evidence"), *aff'd*, 561 F. App'x 327 (5th Cir. 2014) (citations omitted); Fed.R.Civ.P. 60(b)(2).

Consequently, Rule 59(a) governs arguments that a district court committed prejudicial error by preventing the admission of evidence, and/or by committing instructional errors. *See id.* (noting that Rule 59 governs arguments over errors in precluding testimony); *Aero Int'l v. United States Fire Ins. Co.*, 713 F.2d 1106, 1113 (5th Cir. 1983) ("A new trial is the appropriate remedy for prejudicial errors in jury instructions."). To justify a new trial, the error must not have been harmless. *See* Fed. R. Civ. P. 61.

III. ARGUMENT

A. Plaintiff is entitled to a new trial because newly discovered evidence generated by Bayer scientists regarding the use of Neoplastin PT and anti-Factor Xa assays to assess Xarelto's anticoagulant effect would probably have changed the outcome of trial.

A new study conducted by leading Bayer scientists that was not published until after the *Mingo* trial was reaching its conclusion contains striking new evidence regarding the use of Neoplastin PT and anti-Factor Xa assays to assess Xarelto's anticoagulant effect.[1] The *Kreutz* article reports on an underlying study funded by Bayer AG that evaluated and compared the anticoagulant effects of rivaroxaban (Xarelto) and apixaban (Eliquis) at the respective doses approved for each drug's A-fib indication.[2] The secondary objective of the underlying study was to "examine corresponding surrogate measures of the effectiveness of the drugs, namely anti-FXa activity, thrombin generation, PT and aPTT, and to explore their relationship with the plasma concentration of both drugs," and the authors note that "[t]hese data will help further inform physician decisions regarding DOACs and the appropriate dosing regimen."[3] The STA Neoplastin CI Plus reagent, the same reagent used to measure Ms. Mingo's PT, was used for PT assessments in the study.[4]

The conclusion of the *Kreutz* article states that "[s]ensitive prothrombin time and activated partial thromboplastin time assays can be used to estimate the anticoagulant effects of rivaroxaban."[5] Further, the article states that "global screening assays, such as prothrombin time (PT) and activated partial thromboplastin time (aPTT) may be used to assess the anticoagulant activity and have been shown to be sensitive to rivaroxaban."[6] Figure 6 in the *Kreutz* article

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[1] Kreutz, R., Persson, P. B., Kubitza, D., Thelen, K., Heitmeier, S., Schwers, S., Becka, M. and Hemmrich, M., *Dissociation between the pharmacokinetics and pharmacodynamics of once-daily rivaroxaban and twice-daily apixaban: a randomized crossover study*, J THROMB HAEMOST. Accepted Author Manuscript. doi:10.1111/jth.13801 (Aug. 14, 2017) (Attached hereto as "Exhibit 1.") [hereafter "*Kreutz*"].

[2] Exhibit 1, at 2, 18; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 3 and 4.

[3] Exhibit 1, at 5-6.

[4] Exhibit 1, at 9; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 6.

[5] Exhibit 1, at 3; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para 9.

[6] Exhibit 1, at 5; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para 9.

demonstrates Xarelto's effects on PT.[7] In noting that the finding that Xarelto exhibits a clear prolongation of PT is in agreement with other recently published data, the authors referenced an article published by Plaintiff's expert Robert Gosselin.[8] Further, the authors state that "in some clinical situations (such as medical emergencies that require prompt decision-making) it may still be beneficial to assess the extent of drug exposure and how this relates to anticoagulant effect."[9] Thus, not only does the new evidence establish that Neoplastin PT can be used to assess Xarelto's anticoagulant effect, it also supports the position that it may be beneficial to do so in some clinical settings. Additionally, the authors acknowledged the close relationship between the plasma concentration-time profiles and the anti-Factor Xa activity of rivaroxaban, which supports Plaintiff's design defect claim.[10] The data from the underlying study "supports the use of chromogenic anti-FXa assays to estimate plasma concentrations."[11]

The fact that new scientific support for Plaintiff's Neoplastin PT position at trial emerged just as the trial was concluding is in and of itself important; but the fact that this support emanated from a study conducted by Defendants' own scientists gives rise to the very relief justified under Rule 59. Six of the eight scientists who conducted the study and co-authored the *Kreutz* article are Bayer scientists[12], including Dagmar Kubitza, who is the Clinical Pharmacology Lead for Xarelto and the Head of the Pharmacodynamics Department in Clinical Pharmacology.[13] The other two

[7] Exhibit 1, at 21-22, 29; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 8.

[8] Exhibit 1, at 16, n.13.

[9] *Id.* at 16.

[10] *Id.*

[11] *Id.;* Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 11.

[12] Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 3; Exhibit 1, at 18 (The Bayer scientists who conducted the study and co-authored the article at issue are D. Kubitza, K. Thelen, S. Heitmeier, S. Schwers, M. Becka, and M. Hemmrich).

[13] Exhibit 3, Deposition of Dagmar Kubitza, 12:22-13:4.

authors have worked as consultants for Bayer companies.[14] Significantly, the study findings and statements in the article directly contradict Xarelto's prescribing information and key representations Defendants' were simultaneously making to the Court and jury through counsel and expert witnesses during the *Mingo* trial. This study and article constitute material new evidence which was not available prior to the discovery deadline and undermines the results of the *Mingo* trial and would likely result in a different outcome if Plaintiff had the opportunity to investigate this matter further in advance of the trial.

The 5th Circuit has recognized that "newly discovered evidence" by a party may serve as grounds for granting a new trial. *See Diaz v. Methodist Hosp.*, 46 F.3d 492, 495 (5th Cir. 1995) (citing *Johnston v. Lucas*, 786 F.2d 1254, 1257 (5th Cir.1986)). In deciding whether newly discovered evidence is sufficient to warrant a new trial under Rule 59(a), "the district court should consider whether the evidence: (1) would probably have changed the outcome of the trial; (2) could have been discovered earlier with due diligence; and (3) is merely cumulative or impeaching. *Id.* at 495 (citing *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 917 (5th Cir. 1987), *Johnston*, 786 F.2d at 1257, and *La Fever, Inc. v. All-Star Ins. Corp.*, 571 F.2d 1367, 1368 (5th Cir. 1978)). The burden is on the movant to demonstrate that the new evidence "clearly weighs in favor of a new trial." *Randle*, 2016 WL 760770, at *2 (citing *Diaz*, 46 F.3d at 495). The decision to grant or deny a motion for a new trial is within the sound discretion of the trial court. *Id.* (citing *Pryor v. Trane Company*, 138 F.3d 1024, 1026 (5th Cir. 1998)).

1. The new evidence contained in the *Kreutz* article would have probably changed the outcome of the *Mingo* trial.

[14] Exhibit 1, at 18; Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 3.

The new evidence at issue is not just material, it is critical to Plaintiff's case and would have probably changed the outcome of the trial. Plaintiff's failure to instruct claim was based on Defendants' failure to instruct doctors that Xarelto's anticoagulant effect could be measured with standard laboratory testing, including Neoplastin PT. This new evidence contradicts Xarelto's product label that specifically informed doctors that "[t]he anticoagulant effect of XARELTO cannot be monitored with standard laboratory testing nor readily reversed."[15] Further, the new evidence in the *Kreutz* article confirms and supports one of Plaintiff's key positions and shows that Defendants' own scientists currently agree with Plaintiff's position that Neoplastin PT can be used to assess Xarelto's anticoagulant effect in patients.[16] Even more, as Dr. Henry Rinder states in the attached affidavit, this study shows that Defendants' own scientist currently use Neoplastin PT to assess Xarelto's anticoagulant effect in patients.[17] Additionally, the *Kreutz* article supports Plaintiff's position regarding the use of anti-Factor Xa assays to assess Xarelto's anticoagulant effect, which was the basis of Plaintiff's design defect claim.

This new evidence renders Defendants' expert testimony on issues material to the outcome of the case to be scientifically inaccurate and misleading to the Court and the jury. For example, Defense expert Dr. Demondes Haynes told the jury that PT is not a useful test for monitoring Xarelto and is not useful when treating patients on Xarelto.[18] Dr. Haynes told the jury that relying on PT for patients taking Xarelto could be dangerous.[19] Each of those statements by Dr. Haynes contradict the new evidence released by Bayer scientists. Another Defense expert, Dr. Vincent

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[15] Exhibit 4, January 2015 Xarelto Prescribing Information, p. 10, section 5.7.

[16] *See* Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 10.

[17] *Id.*

[18] Trial Transcript at 1857:15-19. [hereafter "Trial Tr."] (excerpts attached hereto as "Exhibit 5").

[19] *Id.* at 1915:24-1916:9

Herrin, told the jury that PT testing for patients on Xarelto is not helpful and could cause harm to patients.[20] Dr. Herrin testified that PT cannot be used to determine the anticoagulant effect of Xarelto in a patient's body.[21] He told the jury that PT "does not provide a reliable measure whatsoever of the amount of exposure to Xarelto in any given patient or at any given point in time during his/her anticoagulation therapy."[22] Finally, Dr. Herrin told the jury that PT results are "meaningless" numbers.[23] Thus, Defendants were telling the Court and jury in the *Mingo* case that PT is dangerous, useless, and meaningless, while simultaneously saying something completely different in the medical literature. This evidence was not available to cross-examine these witnesses, which further prejudiced Ms. Mingo.

2. Plaintiff could not have obtained the new evidence before trial, regardless of due diligence.

The *Kreutz* article and the evidence contained therein simply could not have been discovered before trial, as it was not publicly available, regardless of Plaintiff counsels' due diligence. The Bayer-funded and authored article was not released or available to the public until the second week of trial, being released online as an "accepted article" on August 14, 2017.[24] Thus, Plaintiff counsel could not have discovered this evidence prior to trial, which started on August 7, 2017. Plaintiff's counsel's due diligence goes beyond traditional discovery methods and includes regular monitoring of medical literature related to Xarelto and subscribing to services

[20] *Id.* at 2018:16-2019:6.

[21] *Id.*

[22] *Id.* at 2076:25-2077:4.

[23] *Id.* at 2039:25-2040:5, 2201:8-12.

[24] Exhibit 2, Affidavit of Henry M. Rinder, MD, at para. 2; *See* Exhibit 6, also available at: http://onlinelibrary.wiley.com/doi/10.1111/jth.13801/abstract?systemMessage=Wiley+Online+Library+will+be+unavailable+on+Saturday+and+Sunday+i.e+16th+and+17th+September+at+3%3A00+EDT+%2F+8%3A00+BST+%2F+12%3A30+IST+%2F+15%3A00+SGT+for+5+hours+and+3hours+for+essential+maintenance.+Apologies+for+any+inconvenience+caused+.

that provide alerts when new articles regarding Xarelto are published. Even with those efforts, though, Plaintiff's counsel did not receive notice of the existence of the *Kreutz* article until the morning of closing statements in the *Mingo* trial, August 18, 2017, after the evidence was already closed. Because of the timing, it was only after the verdict that Plaintiff's trial counsel could fully review the article and determine its applicability and significance to Ms. Mingo's case. Thus, for all practical purposes, the new evidence contained in the article at issue was not discovered until after trial. Despite counsel's extensive discovery and due diligence in staying abreast of relevant medical literature, the new evidence at issue could not reasonably have been discovered earlier for use at trial.

3. The *Kreutz* article is material new evidence that is not merely cumulative or impeaching.

As set forth above, the new evidence contained in the Kreutz article is crucial to Plaintiff's case, and presentation of that evidence to the jury would probably have changed the outcome of the *Mingo* trial. Although Plaintiff argued at trial that Neoplastin PT could be used to measure Xarelto's anticoagulant effect and presented evidence to that effect, this new evidence is not merely "cumulative." Additionally, although the new evidence may effectively impeach key testimony from defense experts, the new evidence is not merely "impeaching." Rather, the new evidence from the *Kreutz* article goes to the core of Plaintiff's claim. It is striking new evidence that shows that Defendants' own scientists currently and actively hold the position Neoplastin PT can be used to assess Xarelto's anticoagulant effect. This is recent, up-to-date scientific data that confirms Plaintiff's argument on this critical issue. Furthermore, this new evidence renders much of Defendants' in-court arguments and expert testimony on issues critical to the outcome of the case as scientifically inaccurate and misleading to the Court and jury. Presentation of this new evidence would not constitute mere cumulation or impeachment, but the inability of Plaintiff to

present this evidence to the jury and cross-examine Defendants' witnesses with this evidence would be unfairly prejudicial to Plaintiff Dora Mingo. Accordingly, for the reasons set forth above, Plaintiff Dora Mingo is entitled to a new trial based on the discovery of new evidence.

B. Plaintiff is entitled to a new trial because Defendants disregarded this Court's *In Limine* ruling regarding a Prothrombin Time test being specifically approved by the FDA for use with Xarelto, and Plaintiff's request for a curative instruction about this ruling was not provided.

Prior to trial, Plaintiff Mingo moved *in limine* for an order prohibiting testimony intended to confuse the jury about the false need to have the FDA approve PT Neoplastin as a reagent for the specific purpose of testing PT associated Xarelto users.[25] This Court granted the motion, as follows:

> Whether the FDA approved Neoplastin PT or not is not the ultimate issue – the Defendants have not shown they gave the FDA sufficient information to adequately decide whether or not Neoplastin PT should be used with Xarelto. Accordingly, Plaintiffs' motion is **SUSTAINED**.[26]

During the trial, however, the Defendants' simply ignored this Court's ruling. For example, during the cross-examination of Robert Gosselin, Mr. Sarver violated the order by asking:

> Q. Have you read the Neoplastin CI Plus package insert?
> A. Yes.
> Q. And you know, based on reading it, that is not approved for use with Xarelto?[27]

[25] *See* Plaintiff's Motion in Limine No. 37 to Preclude the False and Misleading Argument that a Prothrombin Time (PT) Test Must Be Specifically Approved by the FDA for Use with Xarelto (Record Doc. 6492). This motion, and its supporting memorandum and exhibits, are incorporated herein by reference.

[26] *See* Order and Reasons of May 26, 2017 at 16 (Rec. Doc. 6645).

[27] Trial Tr., 839:2-6.

Because the loaded question was intended to confuse the jury, Mr. Gosselin was only able to respond by saying that, "I don't think the package insert says anything its approved for any use."[28]

Emboldened by this foray into prohibited territory, Mr. Sarver then exacerbated the prejudicial impact of ignoring the Court's *in limine* ruling by suggesting to the jury that the absence of FDA approval for an anti-Factor Xa assay was also relevant and to be considered. Specifically, Mr. Sarver improperly interrogated Mr. Gosselin as follows:

> Q. Currently, there are no FDA-approved commercial rivaroxaban-specific calibrators or controls available for use in the United States, and that includes the Factor Xa assay?
>
> A. Well, again, I'm not sure that the FDA needs to validate a particular kit for measuring anti-Xa, but again, that's a regulatory issue. But certainly there are no FDA-approved calibrators and controls.
>
> ***
>
> Q. You used the Factor Xa Assay?
>
> A. I used an FDA-approved Factor Xa-assay.
>
> Q. But not for Xarelto. The FDA has never approved a Factor Xa assay for Xarelto, as of today?
>
> A. Again, I'm not sure of the regulatory issues, if it needs to be approved specifically for Xarelto or any anit-Xa because the test does measure anti-Xa. I'm not sure of the approval process for each kind of drug. I'm not sure of the regulatory issues.[29]

When Plaintiff objected about these abuses of the Court's ruling, the Court recognized the violation and resolved the matter by inviting Plaintiff to request a proper corrective instruction.[30] However, in response to Mr. Birchfield's request for an instruction specifically addressed to the needlessness of FDA's specific approval of PT Neoplastin for use with Xarelto, the Court

[28] *Id.* at 839:7-8.

[29] Trial Tr. at 861:19-25; 862:23-863:6.

[30] *Id.* at 898:12-899:3.

(apparently unaware of Plaintiff's proposed instruction) instead inconsistent with its pretrial ruling instructed the jury about a manufacturer's responsibility for a drug's label:

> MR. BIRCHFIELD: Before -- before the witness is sworn in, we would ask the Court to give an instruction regarding the Neoplastin PT and the FDA approval.
> THE COURT: Well, with regard to --
> MR. SARVER: Your Honor, we object to the language that is proposed by the plaintiffs.
> THE COURT: I don't know what language they proposed.
> MR. SARVER: Okay. Thanks, Judge. Sorry.
> THE COURT: With regard to -- we've heard the FDA approval with regard to labels, and you should know that the defendant at all times has the responsibility of providing an adequate label to warn and instruct treaters on prescription drugs. In fact, any action, or actually inaction, on the part of the FDA, though relevant, does not foreclose a claim under Mississippi law. In other words, it's relevant, but not dispositive.
>
> Let's proceed.[31]

Plaintiff Dora Mingo was prejudiced by this ineffectual instruction. Rather than advise the jury of its *in limine* ruling to the effect that "Whether the FDA approved Neoplastin PT or not is not the ultimate issue – the Defendants have not shown they gave the FDA sufficient information to adequately decide whether or not Neoplastin PT should be used with Xarelto," the Court's instruction about the manufacturer being responsible for its label failed to correct the infraction. The jury was never instructed that PT Neoplastin did not have to be specifically approved by the FDA to be tested in conjunction with Xarelto, or, for that matter, employed to the same effect for the anti-Factor Xa assay.

It was error for this Court to permit the Defendants to run roughshod over its *in limine* ruling, and to instead leave the jury with the misimpression at the time of the infraction that without

[31] *Id.* at 899:17-900:8.

FDA approval of Neoplastin PT specifically for use with Xarelto, the Defendants would have been prohibited or it would be impossible for anyone to use Neoplastin PT to perform PT testing on Xarelto patients. The Court compounded this error by later refusing to give the promised curative instruction even in its closing instructions to the jury.[32]

Under Fed.R.Evid. 403, allowing this confusing testimony was extraordinarily prejudicial,[33] and thus affected the substantial rights of Plaintiff Dora Mingo. For this reason alone, a new trial should be granted.

C. Plaintiff is entitled to a new trial because admitting the Strike Through Document was highly prejudicial, and that prejudice was exacerbated by the Court's failure to properly instruct the jury of the Defendants' burden to prove by 'clear evidence' that FDA would not ever have approved such language.

From the outset of the trial, it was obvious that the Defendants would seek to employ the regulatory environment created by the FDA to their greatest advantage. From their opening argument onwards, the Defendants played the "FDA card."[34] Without doubt, the proof of any pharmaceutical case will involve the relevant activities of the FDA. In this case, however, after the Court had already denied the Defendants' motion for summary judgment regarding preemption,[35] the Defendants continued to infuse the trial with irrelevant FDA issues of implied preemption.

[32] *See* Trial Tr. at 2138:3 – 10.

[33] To be sure, the Defendants did not fail to point out the lack of FDA approval specific to Xarelto for the anti-Factor Xa assay in their closing argument. *See* Trial. Tr. at 2181:19.

[34] *See, e.g.*, Trial Tr. at 171:2-7 ("We know that the FDA, even today, does not recommend using a PT test for doctors to tell them what effect Xarelto is having in a patient's blood because they know that it doesn't predict the risk of bleeding.").

[35] *See* Order and Reasons of July 21, 2017 (Rec. Doc. 7110).

In particular, the Defendants continued to place "front and center" the so-called "Strike Through" document, a red-lined Microsoft Word document, which is an edited version of a June 2011 draft labeling for the VTE prevention indication, and based on the RECORD study. This document contains redlines in "Track Changes" by anonymous authors that strike-through proposed language in Section 12 of the label, relating to the reporting of the 5th and 95th Percentile PT values from the RECORD studies, as well as basic guidance that if measurement of pharmacodynamics effect is desired, the Neoplastin PT test could be used. Having anonymous authors, the document was rife with foundational deficiencies. Indeed, none of the witnesses at trial had direct first-hand knowledge of the author of the redlines in the Strike Through document, as neither of the two participants of the email exchange between Janssen and the FDA, Andrea Kollath nor Tyree Newman, testified at the trial.

Although preemption had been removed from the parties' trial proofs by virtue of the Court's order denying summary judgment, and no longer relevant, Defendants repeatedly attempted to confront Plaintiff's experts in an effort to have them concede that the redlines were provided by the FDA. Both Dr. Plunket and Dr. Parisian testified that they could not speak with direct knowledge as to the actual author of the anonymous strike throughs.[36] Even the Court recognized this fact.[37] Nevertheless, because the Defendants had obtained a certified copy of the document "red-ribboned" by the FDA, the Court found the document to be self-authenticating and admissible, "because it appears to be what it is."[38]

[36] Trial Tr. at 665:14 – 671:21; 1178:2-1181:14.

[37] *Id*. at 1181:9-14.

[38] *Id.* ("The document is authenticated because it appears to be what it is, a US Food and Drug Administration certificate on it. But who did what, this witness is not able to testify to. I'll admit the document, though.").

But whatever the relevance of the Strike Through document, it pales in comparison to the incredible prejudice it imparted on Plaintiff Dora Mingo. The Defendants were able to argue at closing and mislead the jury into believing that the FDA refused to allow language regarding PT testing, which was at the very heart of Plaintiff's failure to instruct claim. The jury was not charged with Defendants' affirmative defense regarding impossibility preemption, pursuant to *Wyeth v. Levine*;[39] thus, the jury had no reason to review FDA's criticism of the proposed orthopedic label's language. Further, because this Court refused to provide a curative instruction to the jury, the jury was left to speculate as to why the redline appears.

Plaintiff proposed Instruction No. 12 to the Court, which stated:

> You have heard testimony and a document is in evidence concerning certain language proposed by Defendants which was not included in the Xarelto label approved by the FDA. You may give this evidence and this document whatever weight or significance you believe is deserved, including none at all, as is true with all other testimony or documents in evidence in this case.
>
> I further instruct you, however, that evidence seeking to establish that the FDA struck certain language from a proposed Xarelto label does not on its own establish that the FDA would not ever have approved such language, or that the FDA would not ever have approved the type of instructions about Xarelto which Ms. Mingo claims were needed. To establish that the FDA never would have approved such instructions in the Xarelto label, Defendants have the burden under the law to present "clear evidence" this is so.
>
> This burden of proof requires more than a showing of what was likely to occur if the FDA had been presented with the instructions for doctors which Plaintiff claims should have been in the Xarelto label. Instead, the "clear evidence" burden of proof imposed on the Defendants is a demanding standard, one that is greater than the "preponderance of the evidence" burden of proof which applies to the claims brought by Ms. Mingo. To meet a "clear evidence" burden of proof, Defendants must show that it was not only probable, but "highly probable" and "reasonably certain" that the FDA ultimately would have prohibited them from adding language to the Xarelto label in the way the Plaintiff

[39] *Wyeth v. Levine*, 555 U.S. 555 (2009).

> proposes.[40]

This Court declined to provide this instruction, not because it was improper, but because its preference was instead to utilize more general language, *i.e.*, the following instruction:[41]

> I put this sentence in: "In fact, any action or inaction on the part of the FDA, though relevant to your consideration of liability, does not foreclose a claim under Mississippi law. More specifically, if you find that the Defendant failed to apprise prescribing physicians of appropriate testing to address risks that they knew or should have known prior to FDA's approval, or became known or should have become known after FDA approval of the Xarelto label, then FDA approval is not conclusive."
>
> I think that accurately and fully expresses the law. So I'll deny the motion.[42]

Plaintiff submits that this general instruction was not sufficient to encompass the key information set forth in Plaintiff's Proposed Instructions No. 12.

The Court's instructions were not sufficiently clear with regard to what import the jury could attach to any action by the FDA regarding contested language in the warning. In the end, the jurors were not told that they could affirmatively disregard the alleged FDA strike through in determining whether the instructions to treating physicians were inadequate in this case.

Plaintiff further submits that there was no justification to refuse to include the requested instruction. It was not a misstatement of the law or confusing in any way. On the contrary, the most likely effect would have been to clear up potential confusion. Instead, by not being instructed on the weight of the FDA's action *viz.* the label's instructions on the use of PT Neoplastin, jurors

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[40] Rec. Doc. 7149 at 15, citing *In re Xarelto (Rivaroxaban) Prods. Liab. Litig. (Mingo v. Janssen)*, No. 14-md-2592, slip op. (July 21, 2017) [Record Doc. No. 7110], at 11, citing *Wyeth v. Levine*, 555 U.S. 555, 571-72 (2009); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 271, 286 (3d Cir. 2017).

[41] *See* Trial Tr. at 2139:15 – 2140:23.

[42] *Id.* at 2140:13-23. *See also* Jury Instructions at 24-25 (Rec. Doc. 7407).

were not fully advised as to how to consider Plaintiff's key contention. Unfair prejudice is unavoidable in a situation such as this, when a party is required to meet an unclear burden of proof. For this reason alone, a new trial should be granted.

IV. CONCLUSION

Each error listed above, on its own but certainly when considered cumulatively, impaired the substantial rights of Plaintiff Mingo in this trial, and given the significant and unfair prejudice which resulted, Plaintiff is entitled to a new trial. This is especially true in light of newly-published evidence by Defendant Bayer's own scientists, that is not only corroborative of Plaintiff's evidence and presentation at trial, but which likely would have had a profound impact on the cross-examination of key Defendant witnesses, had it been available. Accordingly, a new trial is warranted based on the discovery of new, material evidence that would have probably resulted in a different outcome.

Respectfully submitted,

Dated: September 15, 2017

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[redacted]