

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

**IN RE: XARELTO (RIVAROXABAN) PRODUCTS * MDL NO. 2592
LIABILITY LITIGATION**

* **SECTION L**
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* **JUDGE ELDON E. FALLON**
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* **MAG. JUDGE NORTH**

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THIS DOCUMENT RELATES TO:

Boudreaux v. Bayer Corp., et al. No. 14-2720
Orr, et al. v. Bayer Corp., et al. No. 15-3708

ORDER & REASONS

Before the Court are Plaintiffs' Motions for New Trial Pursuant to Rule 59. R. Docs. 6818, 7047. Defendants have responded in opposition. R. Docs. 7048, 7447. Having reviewed the parties' briefs and the applicable law, the Court now issues this Order & 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 in federal courts throughout the nation against Defendants, Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare AG, Bayer Pharma AG, and Bayer AG, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC, and Johnson & Johnson. The Plaintiffs specifically allege that they or their family members suffered severe bleeding and other injuries due to Xarelto's allegedly inadequate warning label.

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; at present the Court has approximately 20,000 cases in the Xarelto MDL. The Court appointed committees to represent the parties. The Court adopted a discovery plan and set bellwether trials to begin in April 2017. The first two trials involved Louisiana residents: Joseph Boudreux and Sharyn Orr. These trials were conducted in New Orleans, Louisiana. In both the Boudreux and Orr bellwether trials, the juries found for Defendants. Plaintiffs Boudreux and Orr now bring motions for new trial.

II. PRESENT MOTIONS

A. Plaintiff Boudreux's Motion for New Trial (R. Doc. 6818)

Plaintiff has moved for a new trial. R. Doc. 6818. Defendants oppose the motion. R. Doc. 7048. Plaintiff argues that prejudicial errors were committed during trial in evidentiary rulings and jury instructions. R. Doc. 6818-1 at 1. Plaintiff alleges that material evidence was excluded, irrelevant and unfairly prejudicial evidence was admitted, and that accurate jury instructions were rejected. R. Doc. 6818-1 at 1. Plaintiff claims that each of these errors affected their rights and therefore, Plaintiff is entitled to a new trial. R. Doc. 6818-1 at 1.

Plaintiff argues that prohibition of placing a medical article referred to as the "Lippi Article" and information regarding foreign labels was prejudicial. R. Doc. 6818-1 at 3, 7. Plaintiff also alleges that allowing evidence of personal use of Xarelto by expert's family

members was prejudicial. R. Doc. 6818-1 at 14. Finally, Plaintiff argues that it was error to use a general jury instruction and that Defendant's demonstrative materials should not have gone to the jury room. R. Doc. 6818-1 at 17, 20.

B. Defendant's Response (R. Doc. 7048)

Defendant responds arguing that Plaintiff's arguments are without merit, that most of them were not adequately preserved, and that there will be no "manifest injustice" resulting from the verdict. R. Doc. 7048 at 1. First, Defendant alleges that Plaintiff's claims regarding the exclusion of evidence from foreign medical associations, information from foreign Xarelto labels, and requested jury instructions were not preserved. R. Doc. 70448 at 1-3. Second, Defendant argues that the Court did not abuse its discretion by allowing Dr. Peter's testimony regarding his wife's use of Xarelto and that this testimony did not substantially affect Plaintiff's rights because Plaintiff cross-examined Dr. Peter's regarding this testimony. R. Doc. 7048 at 2. Finally, Defendant argues that it was not error for the Court to allow some exhibits to be shown to the jury during their deliberations, and that Plaintiff consented to this submission. R. Doc. 7048 at 3.

C. Plaintiff Orr's Motion for New Trial (R. Doc. 7047)

Plaintiffs have moved for a new trial. R. Doc. 7047. Defendants oppose the motion. R. Doc. 7447. Plaintiffs argue that prejudicial errors were committed during trial in evidentiary rulings and jury instructions. R. Doc. 7047-1 at 1. Plaintiffs allege that material evidence was excluded, irrelevant and unfairly prejudicial evidence was admitted, and that accurate jury

instructions were rejected. R. Doc. 7047-1 at 1. Plaintiffs claim that each of these errors affected their rights and therefore, Plaintiffs are entitled to a new trial. R. Doc. 7047-1 at 1.

First, Plaintiffs argue that the exclusion from evidence of language on the Xarelto label in Canada was a prejudicial error that affected their rights. R. Doc. 7047-1 at 5. Plaintiffs argue that excluding these labels because they are foreign is not required. R. Doc. 7047-1 at 4. Second, Plaintiffs argue that relevant statements from business records were precluded in error. R. Doc. 7047-1 at 5. Plaintiffs allege that this error was not harmless because it would have challenged important defense testimony and established Bayer's knowledge of the benefits of PT testing, in dispute at the trial. R. Doc. 7047-1 at 6. Finally, Plaintiffs argue that there were confusing errors in the jury instructions. R. Doc. 7047-1 at 7. Plaintiffs suggest that the more general jury instruction provided was not adequate to deal with the important and complex information provided to the jury. R. Doc. 7047-1 at 9.

D. Defendant's Response (R. Doc. 7447)

Defendants respond arguing, first, that the Court did not abuse its discretion by finding that the foreign labels and regulations were irrelevant. R. Doc. 7447 at 1. Defendants further argue that this ruling did not substantially affect the outcome of the trial because Plaintiffs were able to cross-examine Defendants' expert witnesses about statements made outside the United States. R. Doc. 7447 at 1-2. Second, Defendants argue that Plaintiffs did not meet their burden of showing that the business records exception applied to the document in question and that this exclusion was not prejudicial because Plaintiffs were permitted to ask witnesses about the contents of the document. R. Doc. 7447 at 2. Finally, Defendants argue that Plaintiffs are not entitled to a new trial based on the Court's choice of jury instructions. R. Doc. 7447 at 2-3.

III. LEGAL STANDARD

Plaintiffs seek new trials pursuant to Federal Rule of Civil Procedure 59. Federal Rule of Civil Procedure 59(a)(1)(A) provides that “[t]he court may, on motion, grant a new trial on all or some of the issues—and to any party—as follows: after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court.” 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.” *Smith v. Transworld Drilling Co.*, 773 F.2d 610, 613 (5th Cir. 1985) (citations omitted); *see also McFadden v. Wal-Mart Stores*, No. 04-2547, 2006 WL 3087164, at *2 (E.D. La. Oct. 27, 2006). “A district court, however, should attempt to avoid substituting its judgment for the jury’s considered verdict, so as to not violate the parties’ Seventh Amendment rights.” *Lapapa v. National Railroad Passenger Corp.*, No. 04-1125, 2005 WL 3533858, at *3 (E.D. La. Oct. 19, 2005). And to be granted a new trial, the plaintiff must demonstrate that “manifest injustice will result from letting the verdict stand.” *Learnmonth v. Sears, Roebuck & Co.*, 631 F.3d 724, 731 (5th Cir. 2011). Furthermore, in order for an error to justify a new trial, the error must not have been harmless. Fed. R. Civ. P. 61.

IV. DISCUSSION

The Fifth Circuit has repeatedly held that “the decision to grant or deny a motion for new trial generally is within the sound discretion of the trial court and will not be disturbed unless there is an abuse of that discretion or a misapprehension of the law.” *Dixon v. International Harvester Co.*, 754 F.2d 573, 586 (5th Cir. 1985). *See Prytania Park Hotel, Ltd. v. General Star Indemnity Co.*, 179 F.3d 169, 175 (5th Cir. 1999); *Mitchell v. Lone Star Ammunition, Inc.*, 913 F.2d 242, 252 (5th Cir. 1990); *Shows v. Jamison Bedding, Inc.*, 671 F.2d 927, 930 (5th Cir. 1982); *Evers v. Equifax, Inc.*, 650 F.2d 793, 796 (5th Cir. 1981). Modifying or setting aside a judgment

under Rule 59 is an extraordinary remedy; motions for new trial or to alter or amend a judgment should not be avenues for relitigating old matters, raising new arguments, or submitting evidence that could have been presented before. *See Theriot v. Parish of Jefferson*, 66 F. Supp. 1435, 1452 (E.D. La. 1997); *Campbell v. St. Tammany Parish School Board*, No. 98-2605, 1999 WL 777720, at *1 (E.D. La. Sept. 29, 1999).

The Court is cognizant of the impact evidentiary rulings and other Court decisions can have on the course of a trial. Therefore, the Court carefully considers these decisions and strives for equity as well as compliance with the Federal Rules. In these cases, the Court finds that no harmful errors were made to the prejudice of the plaintiffs.

A. Plaintiff Boudreaux's Motion

i. Prohibition of Article in Evidence

Plaintiff argues that exclusion of the Lippi article from evidence was a prejudicial error. In its Order and Reasons regarding Defendants' motion in limine, the Court reasoned that any evidence relating to foreign labels or foreign regulation was likely excludable under Federal Rules of Evidence 401 and 403. R. Doc. 6254 at 13-14. At trial, the Court found the information in the article in question, the Lippi article, was related to foreign labelling and regulation. The Court was concerned that the jury would be confused by references to foreign regulations and standards because the jury must decide the case based on standards in the United States. The Court has consistently excluded evidence related to foreign regulations under Rule 403. Therefore, the Court held that the evidence was inadmissible because it would be confusing to the jury. Furthermore, Plaintiff was afforded multiple opportunities to cross-examine Defendant's expert witnesses regarding academic thought on PT testing in conjunction with

Xarelto and therefore, was not prejudiced by this decision. Exclusion of this evidence under Rule 403 was not error.

ii. Foreign Labels

Plaintiff argues that exclusion of foreign Xarelto labels was a prejudicial error. As stated above the Court has held that information on foreign Xarelto labels is irrelevant and could be confusing to a jury. The Court has consistently held that “what [Defendants] put on Xarelto’s label in other countries in order to comply with foreign regulatory bodies or agencies” is not admissible. R. Doc. 6645 at 11-13. Exclusion of this evidence under Rules 401 and 403 was not error. Furthermore, the Court allowed Plaintiffs to utilize the statements made by the Defendant to foreign authorities on the basis of Rules 613 and 801(d)(2). Thus, no prejudice resulted.

iii. Evidence Regarding Personal Use of Xarelto

Plaintiff argues that it was prejudicial error to allow testimony of Dr. Gary Peters regarding his wife’s use of Xarelto. The Court agreed that, in general, such evidence would be irrelevant and prejudicial. However, the Court alerted the parties that this evidence may become relevant to the credibility of an expert witness. The Court allowed personal use testimony in this narrow context. The Court reasoned that Plaintiff placed Dr. Peters’ credibility in issue when Plaintiff suggested that Dr. Peters made choices for financial gain rather than patient safety. Furthermore, Plaintiff was permitted to cross-examine Dr. Peters regarding this testimony. Therefore, allowing this testimony was not prejudicial error.

iv. Jury Instructions

Plaintiff argues that it was prejudicial error for the Court to decline to use Plaintiff’s proposed jury instructions. Jury instructions must be “comprehensive, balanced, fundamentally accurate, and not likely to confuse or mislead the jury.” *Sommers Drug Stores Co. Employee*

Profit Sharing Tr. v. Corrigan, 883 F.2d 345, 350 (5th Cir. 1989). In choosing the jury instructions, the Court reasoned that the jury charge should focus on the governing law as a whole (comprehensively), rather than on a specific part of the law. Additionally, the Court included reference to the federal regulations as requested by Plaintiff. Here, the jury instructions were comprehensive and were not confusing or misleading. Therefore, the Court finds that declining Plaintiff's proposed jury instructions was not error.

v. Demonstrative Materials

Plaintiff argues that it was prejudicial error to send demonstrative materials to the jury room. At trial the parties discussed which materials should be sent to the jury room. Upon reaching an agreement, both parties signed off on the materials. Plaintiff alleges that some materials not agreed upon were sent to the jury room. However, the Court has set up a specific process allowing both parties to sign-off on materials sent to the jury. Furthermore, the Court may submit demonstrative materials to the jury, without agreement of the parties, if the Court also provides the jury with "careful cautionary instructions as to their use and limited significance." *Big John, B.V. v. Indian Head Grain Co.*, 718 F.2d 143, 148-49 (5th Cir. 1991). Here, the Court provided such instruction to the jury after providing the demonstrative materials. Therefore, the Court finds no error.

B. Plaintiff Orr's Motion

i. Foreign Labels

Plaintiff Orr also argues that exclusion of foreign Xarelto labels was a prejudicial error. As stated above the Court has held that information on foreign Xarelto labels is irrelevant and could be confusing to a jury. The Court has consistently held that "what [Defendants] put on Xarelto's label in other countries in order to comply with foreign regulatory bodies or agencies"

is not admissible. R. Doc. 6645 at 11-13. Exclusion of this evidence under Rules 401 and 403 was not error.

ii. Business Records

Plaintiff argues that exclusion of an email with an attached document was error because the email qualified as a business record under Federal Rule of Evidence 803(6). The excluded email contained communication between employees of Defendant Janssen regarding foreign regulations. The Court held that the attached document would not be allowed into evidence because of its relation to foreign regulation; however, Plaintiff was permitted to use the document to question Defendants' witnesses about their knowledge. The Court reasoned that this ruling was a balance between allowing relevant evidence of Defendants' knowledge and excluding irrelevant information about foreign regulation. The Court further held that the attachment could not come in as a business record because the witness could not recall reading it. Email documents are not automatically business records because they are sent to a business address. In order for an email to become a business record, the email must be acted upon in some manner in the course of business. Here, Plaintiffs provided no foundation that the email and attachment were read or otherwise acted upon. Therefore, these rulings were not error.

iii. Jury Instructions

Plaintiff Orr also argues that it was prejudicial error to decline to use Plaintiff's proposed jury instructions. As outlined above, the Court finds that declining Plaintiff's proposed jury instructions was not error.

After considering the parties' arguments, the Court finds that Plaintiffs have not demonstrated errors of law or fact, newly discovered or previously unavailable evidence, any

manifest injustice or an intervening change in controlling law that require this Court to grant a new trial.

V. CONCLUSION

For the aforementioned reasons, **IT IS ORDERED** that the Plaintiffs' Motions for New Trial, R. Docs. 6818, 7047, are hereby **DENIED**.

New Orleans, Louisiana, this 20th day of September, 2017.



UNITED STATES DISTRICT JUDGE