UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	*	MDL 2592
	*	SECTION L
THIS DOCUMENT RELATES TO ALL CASES	*	JUDGE ELDON E. FALLON
	*	MAG. JUDGE NORTH

* *

PLAINTIFFS' STEERING COMMITTEE'S REPLY TO DEFENDANTS' OPPOSITION TO MOTION TO CHALLENGE CONFIDENTIALITY DESIGNATIONS AND FOR RELIEF FROM PRETRIAL ORDER NO. 12 (STIPULATED PROTECTIVE ORDER)

The PSC respectfully submits this reply to Defendants' Opposition to the PSC's Motion to Challenge Confidentiality Designations and For Relief from Pretrial Order No. 12 (Stipulated Protective Order).

I. INTRODUCTION

The PSC moved to challenge the confidentiality designations of documents recently produced in this litigation because of their relevance to ongoing inquiries into the integrity of the ROCKET AF clinical trial that supported the approval and launch of Xarelto. In opposing the motion, Defendants attempt to cloud the true public safety issues at stake with claims that the motion was only a ploy to attract media attention. Yet, until the motion, Defendants had shown no proclivity on their own to take any action to further disclose information relevant to investigations into use of the defective Alere (Hemosense) INRatio® point-of-care ("POC") device in the ROCKET AF trial.

As it stands, Defendants only provided some of the documents at issue in the motion to the Food and Drug Administration ("FDA") just *one* day prior to filing their response to the motion in order to give the false impression that a full disclosure was made. When examined

closely, however, the dismissive opposition in fact demonstrates the PSC's point that Defendants withheld, and are still improperly withholding, information that bears on the ongoing investigations and a full understanding of the INRatio® POC device malfunctions that occurred during the ROCKET AF trial.

As shown, *infra*, the motion is not moot, as Defendants contend. Documents covered by the motion remain undisclosed and ostensibly protected. A partial release of documents to FDA is not the "cure all" that Defendants suggest. *All* documents relevant to this safety issue and the approval of Xarelto should be submitted to FDA.

Moreover, although the investigations by the FDA and the European Medicines Agency ("EMA") prompted the PSC's urgent approach in bringing this matter before the Court, the motion also seeks to declassify the documents as protected so that they are available to others with an interest in public safety. The motion should thus be resolved in the PSC's favor so as to assure: 1) that all information relevant to the INRatio® POC device's use in the ROCKET AF trial is fully accessible to those outside this litigation with an interest in public safety, including, but not limited to the FDA and EMA; and 2) that going forward, over-designation of documents as protected, which occurred here, will not continue.

II. ARGUMENT

A. The FDA, the EMA and the Public Are Entitled to Full Disclosure

Despite having now submitted some of the information at issue in the PSC's motion to the FDA, Defendants argue that the motion improperly seeks to require them "to prematurely disseminate pretrial discovery to federal regulatory agencies and the public at large." Def. Br. at 13. This contention fails to recognize the exigent nature of the PSC's motion, which calls for dissemination of information relevant to *ongoing* investigations into the safety of Defendants'

product. Unlike the information at issue in the cases cited by Defendants, the information here goes not just to the Plaintiffs' claims relating to their use of Xarelto, but also to current investigations into the very premise on which Xarelto was approved.

Defendants should not be allowed to hide behind the over-designation of documents under the Protective Order in this litigation to selectively choose, or in their words "cherry pick," what information to disclose and what information to withhold from regulators seeking information. The documents at issue were discovered in this litigation, but not disclosed to FDA or EMA despite being specifically responsive to the agencies' requests for information on use of the INRatio® POC device in the ROCKET AF trial. The cases cited by Defendants in opposition to the motion are inapposite as they involve no such pending request or investigation. *See, e.g., In Re: Denture Cream Products Liability Litigation*, 2013 U.S. Dist. LEXIS 8114 (S.D. Fla. Jan. 18, 2013) (denying motion to unseal expert reports and documents relied upon by experts where there were no outstanding requests or inquiries from FDA to defendant). Hence, under the circumstances surrounding these documents, the Court should grant the PSC's motion and require full disclosure to the FDA and the EMA.

The general propositions cited by Defendants about the respective role of the courts and the FDA render no support for Defendants' attempts to shield from disclosure critical information on the INRatio® POC device and the ROCKET AF trial. As the Supreme Court observed in *Wyeth v. Levine*, given its limited resources, FDA relies upon drug manufacturers who are obliged to provide it with full information on the safety of their products. 555 U.S. 555, 578-579 (2009). Defendants here have failed to honor their obligation.

Likewise, the public is entitled to know more about the INRatio® POC device's use in the ROCKET AF trial. FDA's Class I recall of the device and the fact that the ROCKET AF

findings are being scrutinized is no secret. When balancing the interests in such circumstances, public safety concerns tip the scales against protecting the information as confidential. *Pansy v. Borough of Stroudsbourg,* 23 F.3d 772, 787 (3d Cir. 1994) ("Circumstances weighing against confidentiality exist when confidentiality is being sought over information important to public health and safety") (citations omitted); *see also Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 780 (1st Cir. 1988) (supporting public access to documents "because of the important public health concerns surrounding the documents in question.").

B. Defendants' Claims of Full Disclosure to FDA Are Unsupported

Among the many unsubstantiated statements in Defendants' opposition, the ones of most concern involve the claims that all of the documents at issue have now been provided to the FDA. *See, e.g.,* Def. Br. at 1 ("[T]he defendants have provided to the FDA the emails and documents that are at issue in this motion."); at 3 ("[D]efendants have provided the entire cherry-picked collection to FDA."); at 11 (On March 7, 2016, Janssen gave to the FDA the remaining portions of those exhibits and Exhibits B, G, I, M, O, Q, R, U, X, Y, BB and CC."). Yet, nowhere in their opposition do Defendants provide proof that *any* of the documents have been delivered to FDA as they assert.[1] Instead, Defendants simply proclaim that all of the documents have been turned over or that FDA is already in possession of the documents. A closer examination, however, reveals that in fact several key documents are missing entirely from those Defendants purport to have released.

In their opposition, Defendants precisely identify documents they have provided to FDA since the filing of the motion, including portions of the PSC's Exhibits E, V, W, and Z, which had not previously been provided, and the entirety of Exhibits B, G, I, M, O, Q, R, U, X, Y, BB

[1] The PSC has requested that Defendants verify exactly what was submitted to FDA, but thus far they have refused to do so.

and CC. Def. Br. at 11. Conspicuously absent from the list, however, are Exhibits K, L, N, P, S and T. For the following reasons, these critical documents should also be released and, along with others at issue, declassified as protected documents.

Exhibit K: This exhibit is a letter from the Duke Clinical Research Institute ("DCRI") to the New England Journal of Medicine ("NEJM"), dated January 11, 2016, responding to the comments of peer-reviewers and the NEJM editors on the Letter to the Editor submitted by DCRI on its recent re-analysis of the ROCKET AF trial. *See* PSC Br. at 6, n.6. Exhibit K sets out the peer-review and editor's comments, as well as DCRI's responses. The comments and responses offer insight and background on the DCRI re-analyses, and they also reveal concerns about the impact of the INRatio® POC device that are not reflected in the published Letter to the Editor. Exhibit K additionally calls into question Defendants' contention that the DCRI re-analysis was an independent study. *See* Def. Br. At 2. In fact, as confirmed in the sworn testimony of Dr. Christopher Nessel (Exhibit L to the motion), Defendants' employees participated in the peer-review and editing process, thereby giving Defendants the opportunity to influence the published results of the so-called "independent" re-analyses. *See* Exh. L at 441:20-455:20.

Exhibit L: Notably, the motion also seeks declassification of Dr. Nessel's deposition transcript (Exhibit L), but like Exhibit K, it too was omitted from the alleged "entire" disclosure to FDA. Yet, Dr. Nessel's testimony is critical to a full understanding of the other documents at issue because it provides explanations that demonstrate the fallacy of Defendants' accusations of "cherry picking." *See, e.g.,* Exhibit L at 178:18-186:2 (Dr. Nessel testifying on Exhibit S; at 195:14-203:7 (Dr. Nessel testifying on Exhibit B); at 441:20-455:20 (Dr. Nessel testifying on

Exhibit K); at 219:19-228:23 (Dr. Nessel testifying on Exhibit T). Indeed, when put in context through the testimony of Dr. Nessel, the significance of the documents is readily apparent.

Other aspects of Exhibit L that are highly relevant to the public safety concerns over the ROCKET AF trial include Dr. Nessel's deposition testimony that members of the ROCKET AF executive committee had concerns about the accuracy of the Hemosense INRatio® device. Exhibit L at 40:10-44:8. He testified that even he was personally worried, while the trial was ongoing, that if the warfarin arm was not properly managed, it could invalidate the study results. Exhibit L at 46:19-52:19.

Dr. Nessel also acknowledged that in late November 2006, he dismissed very grave concerns raised by a Finish neurologist, Dr. Kaste, who cautioned Defendants against the use of a POC device to manage the warfarin arm without first validating the device's performance. Dr. Nessel rejected these concerns claiming that the INRatio® device performed with little "intra- and inter-individual variability" and generated results consistent with a lab method. Exhibit L at 60:8-65:4.

The testimony in Exhibit L further reveals that Dr. Nessel was aware of numerous warning letters received by the INRatio® device manufacturer, which specifically related to instances of the device malfunctioning and providing inaccurate results, but Dr. Nessel had no recollection of sharing this information with other members of the ROCKET AF executive committee. Exhibit L at 77:16-85:17. Dr. Nessel also testified that he was in possession and aware of peer-reviewed literature that indicated the INRatio® POC device was prone to malfunction, and specifically showing that the INRatio® device misidentified 38% of super-therapeutic levels as therapeutic. Exhibit L at 110:10-114:11.

Despite these acknowledgments, Dr. Nessel claimed he first learned of the potential malfunctions of the INRatio® device during the ROCKET AF trial in September, 2015, when contacted by the British Medical Journal. Exhibit L at 123:19-124:3. Dr. Nessel also maintains that there is no direct evidence of device malfunction during the ROCKET AF trial, but his strained definition of malfunction include only instances where there is evidence of the POC generating an inaccurate result to a degree of clinical significance, that resulted in a physician changing dosing behavior and the patient subsequently suffering an adverse event as a result. Exhibit L at 148:10-149:22

Other significant information discovered through Exhibit L includes Dr. Nessel's assertion that the information provided to the FDA about the unblinded monitor was accurate, even though he could not or would not testify that the information was complete—an important distinction given that the FDA was not informed of the fact that the unblinded monitor was the very person responsible for the Covance Recheck Program. Exhibit L at 156:6-164:23. Dr. Nessel was also unable to confirm whether the FDA had ever been made aware of the Covance Recheck Program and he implausibly suggested that it would be irrelevant to the FDA—a point refuted by the fact that FDA has specifically asked for information about the roles and responsibilities of the person in charge of the program. Exhibit L at 171:10-172:23.

The deposition testimony also includes Dr. Nessel's confirmation that he was informed in September of 2007, by Dr. Bill Byra, of evidence that the INRatio® device might be malfunctioning. *See* Exhibit S.[2] He further confirmed that this information was not shared with FDA in response to their January 12, 2016, information request. Exhibit L at 182:6-185:20.

[2] Exhibit S is Exhibit 17 to Dr. Nessel's deposition.

Dr. Nessel also acknowledged in his deposition that the email he received on October 17, 2007, referencing a POC serious adverse event (*see* Exhibit R[3]) is precisely the type of information sought by FDA in their January 12, 2016, information request. After discussing the details of the event as laid out in Exhibit R, Dr. Nessel admitted that although this event was not reported to FDA in response to its recent information request, this might indeed constitute direct evidence of the device malfunction using even his own strained definition. Exhibit L at 186:5-190:24. Dr. Nessel testified to yet another email that he received in October of 2007, discussing another instance of the INRatio® device generating an INR result inconsistent with a non-INRatio® measurement (*see* Exhibit B[4]). There, Dr. DiBittiste (a high ranking Janssen official) opined that the device is defective, but his opinion was not shared with the FDA. Exhibit L at 194:15-200:20.

After being confronted with numerous instances of evidence of the POC device malfunctioning during the ROCKET AF trial, Dr Nessel finally agreed in his deposition that this is exactly the type of information that may be relevant to FDA's January 12, 2016, information request. Yet, it was never shared with FDA. Exhibit L at 213:8-215:9.

Dr. Nessel testified further that in response to the concerns raised by investigators and DCRI, the Covance Recheck Program was initiated and put under the responsibility of the unblinded monitor. He further testified that investigators filed more than 140 reports through the program. Disturbingly, however, Dr. Nessel was unable to confirm whether FDA had ever been made aware of the program or the data generated through it. Exhibit L at 215:12-219:18.

According to Dr. Nessel's testimony, one of the doctors at DCRI, Dr. Becker, had expressed concerns over the accuracy of the INRatio® device and suggested the need to institute

[3] Exhibit R is Exhibit 18 to Dr. Nessel's deposition.
[4] Exhibit B is Exhibit 19 to Dr. Nessel's deposition.

some quality control procedures on its performance. In response, however, Dr. Nessel erroneously told Dr. Becker that the same device has been used in another major Phase III clinical trial (SPORTIF V), which should alleviate his (now known to be legitimate) concerns about the INRatio® device generating inaccurate information. Exhibit L at 264:9-271:17.

Dr. Nessel also confirmed that many initial reports of suspected malfunction were likely missed and not forwarded to the Covance Recheck Program due to procedures in place during the trial. Specifically, when doctors suspected that the device was malfunctioning, they were first encouraged to check the results of one INRatio® device with a second INRatio® device provided to each site. Yet, Dr. Nessel confirmed that every INRatio® device provided to investigators was subject to the recall notice. Accordingly, any assurance placed in the fact that one defective, now recalled, INRatio® device generated a result consistent with another defective, now recalled, INRatio® device would be misplaced. Exhibit L at 302:23-304:16.

Dr. Nessel also testified that in March of 2011, when the FDA asked for performance characteristic data relating to the INRatio® device's use in ROCKET AF, Janssen decided against providing the FDA with the results of the Covance Recheck Program or the results of the week 12 and 24 central lab comparison. Exhibit L at 321:1-322:23. Dr. Nessel's testimony further reveals the secrecy surrounding the Covance Recheck Program in that he was unable to confirm whether or not the Data Safety Monitoring Board, known as the IDMC in ROCKET AF, was made aware of the program. Exhibit L at 361:13-17.

In his deposition testimony, Dr. Nessel also describes the meeting he attended with other members of the ROCKET AF task force on September 21, 2015, where it was discussed that the company had performed an analysis comparing the INRatio® POC data with the central lab data collected at weeks 12 and 24. Dr. Nessel testified that discussions occurred at this meeting on

the fact that the initial trial analyses indicate that, when compared to central lab data, 32% of the samples obtained by the INRatio® POC device were off by 0.5 INR units or more. Exhibit L at 330:12-332:16 (testifying on Deposition Exhibit 40).

A final example of the relevance of Dr. Nessel's testimony calls into question the responses provided to the FDA's and the EMA's recent requests for information on performance of the INRatio® POC device in the ROCKET AF trial. Dr. Nessel admitted in his testimony that, counter to the protocol of the trial and contrary to statements made to FDA and EMA, the blinded sponsor had in fact been provided with aggregate INR time in therapeutic range by the unblinded monitor. Exhibit L at 361:18-365:23.

As shown, Exhibit L is replete with information relevant to the ongoing health and safety investigations into the impact of the INRatio® POC device on the ROCKET AF clinical trial. The significance of this transcript compels that it be disclosed in its entirety to the regulatory agencies and that it be declassified as protected under the Protective Order.

Exhibit N: Exhibit N is also missing from the list of those documents belatedly disclosed by Defendants. This January 23, 2008, email chain relates to a ROCKET AF participant (subject 103804), who had an INRatio® POC INR reading of 2.0 that was subsequently determined through a non-INRatio® POC INR measurement to actually be 10.0. When the POC site reported the inaccurate reading, the site was instructed to return the INRatio® POC device for replacement with a new device. Neither the FDA nor the EMA has been informed of this case, the facts surrounding the discrepant results, or the instructions to replace the device. The disclosure of Exhibit N would provide this highly relevant information.

Exhibit P: Exhibit P, a June 17, 2008, email chain relating to ROCKET AF Site 044002, Patient 105914 also remains to be disclosed to FDA. This document describes another incident

in which the defective INRatio® POC device inaccurately reported a patient's INR. Specifically, the device measured a therapeutic INR value of 2.1, but when measured through the non-INRatio® POC method, the patient's true INR was found to 8.0. Again, no information on this example of the INRatio® POC device has been communicated to regulators.

Exhibit S: Another document, Exhibit S, that was omitted from those released to FDA is a September 25, 2007, email chain discussing problems with the INRatio® POC device at ROCKET AF site 049008. Janssen's Dr. Byra acknowledged in the emails that the device was not functioning properly. Yet, this case of device malfunction was not reported in the submissions provided to regulators prior to Xarelto's approval, nor was it supplied to regulators in conjunction with investigations into the performance of the INRatio® POC device in the ROCKET AF trial.

Exhibit T: Exhibit T is a highly informative spreadsheet, which also remains to be disclosed to FDA, detailing reports of potential device malfunction. This omission is perhaps the most disturbing of all of those absent from the list of documents of identified as submitted to the FDA as a result of the motion. As discussed in Defendants' opposition brief, due to concerns over the accuracy and reliability of the INRatio® POC device, all 1,000 sites participating in the clinical trial were informed of the special Covance Recheck Program. Def. Br. at 6. The program was directed by the unblinded monitor for the purpose of investigating instances of suspected malfunctioning of the INRatio® POC device. *Id.* As discussed in Dr. Nessel's deposition (*see* Exhibit L at 219:19-223:3) and confirmed in Janssen's brief (at 6), cases of possible malfunctions, and concerns over the accuracy and reliability of the device, were reported by 142 of the 1,000 sites in the trial. Exhibit T details those reports, but has not been provided to FDA.

Even more alarming is the fact that the unblinded monitor confirmed upon review of these reports that the device was indeed malfunctioning more than 11% of the time. Def. Br. at 7 (admitting there were 16 confirmed discrepancies between the device INR and lab values). This number would likely be much higher if reduced to warfarin only patients. Notwithstanding the fact that Defendants admit to the existence of the Covance Recheck Program, its intent, and the data generated as a result of this program, they still, to this day, seek to hide this highly significant information. For example, of the 18 reports of apparent malfunctions identified in the PSC's motion (at 9-11), only 4 of the related Exhibits (Exhibits M, O, Q and R) are among those Janssen claims to have now provided to FDA. This is hardly the "full" disclosure that Defendants suggest they conducted.

C. The Challenged Documents Should Be Declassified and Made Available to the Public Because They Are Not Truly Confidential Under the Terms of the Protective Order

The designation of the documents as protected must also be examined by this Court. Contrary to Defendants' assertions, the documents do not truly fall within the categories of confidential documents to be protected under Federal Rule of Civil Procedure 26(c)(1) or the Protective Order entered in this case.

The documents are not entitled to protection merely because they involve assessments and measurements "that are of a highly technical nature," as Defendants argue. Def. Br. at 15-16. Surely, Defendants do not seriously contend that the scientific and medical community is not entitled to full information on the INRatio® POC device and the ROCKET AF trial because in those hands the information might be "misconstrued" or "misinterpreted." Yet, their argument, if accepted, would serve to circumscribe review of the device's performance in the ROCKET AF trial by a broader, and more objective, community of scientists and investigators

than those hand-picked by Defendants. Indeed, public interest investigators, physicians, and in our society even the general public, are entitled to this vital public safety information under the circumstances. *See Pansy*, 23 F.3d at 787; *Public Citizen*, 858 F.2d at 780.

Defendants' attempt to cast the documents as confidential because they "pertain[] to research and development" is likewise without merit. Def. Br. at 16, n.7. The documents do not relate to the type of research and development that qualifies for protection under the Order. As this Court held in *Appalachicola Riverkeeper v. Taylor Energy Co., LLC.*, 309 F.R.D. 381, 389-390 (E.D. La. 2015), documents such as those at issue here, which summarize and inform on the timing and circumstances of events, and even those that constitute investigatory "scientific research," are not protected "research and development" under Rule 26(c), or a Protective Order flowing from the rule.

The documents and information herein differ entirely from what was deemed protected in the cases cited by Defendants. In *Star Scientific, Inc. v. Star Tobacco & Pharm., Inc.*, the court denied a motion seeking disclosure of confidential documents relating only to commercial interests, such as the plaintiff's customer lists, customer purchasing habits, pricing and sales, as well as documents relating to the manner in which the company operated and managed the processing of its products. 204 F.R.D. 410, 415-416 (S.D. Ind. 2001). Likewise, in *Containment Techs Group, Inc. v. Am. Soc'y of Health Sys. Pharmacists*, the Protective Order at issue did not allow for protection of documents simply because of the "significant time and money" spent on developing the product, as Defendants suggest. Def. Br. at 16, n.7, citing *Containment Techs*, No. 07-997, 2008 WL 4545310, at *1-2 (S.D. Ind. Oct. 10, 2008). Rather, the court in that case agreed to entry of a Protective Order with terms that limited the designation of documents as confidential to those involving "trade secrets," including "research and development data,

pricing information, financial data, and the identity and lists of customers and vendors," and also because the order included provisions allowing the public to challenge the sealing of documents. The protections afforded in *Containment Techs* involved commercial matters only and did not provide for protection of information relevant to a pressing issue of public health.

Defendants' sweeping designation of virtually all documents produced and testimony provided in this litigation as protected is unwarranted. As shown, the confidential status of the documents and information at issue in the PSC's motion are not entitled to such protection.

II. CONCLUSION

For the reasons set forth in the motion, and herein, the PSC respectfully requests that the Court grant its motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 11, 2016, the foregoing pleading was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to Liaison Counsel for Plaintiffs and Defendants by operation of the court's electronic filing system and served on all other plaintiff counsel via MDL Centrality, which will send notice of electronic filing in accordance with the procedures established in MDL 2592 pursuant to Pre-Trial Order No. 17.

/s/ Leonard A. Davis
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